



Risk regulation at international, European and national level

The European Chemicals Agency
- Beyond the Scope of the *Meroni* Doctrine? -

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List of Abbreviations

BSE	Bovine Spongiform Encephalopathy
CFI	Court of First Instance
CPMP	Committee for Proprietary Medicinal Products
CPS&Q	Consumer Product Safety and Quality
CPVO	Community Plant Variety Office
CRA	Committee for Risk Assessment
CSA	Committee for Socio-economic Analysis
CTM	Community Trade Mark
EASA	European Aviation Safety Agency
EC	European Community
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECSC	European Coal and Steel Community
EEA	European Environment Agency
EEC	European Economic Community
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EP	European Parliament
EU	European Union
NCAs	National Competent Authorities
NRAs	National Regulatory Authorities
OHIM	Office for Harmonisation in the Internal Market
OJ	Official Journal
OLAF	European Anti-Fraud Office
RCD	Registered Community Design
REACH	Registration, Evaluation and Authorisation of Chemicals
TFEU	Treaty on the Functioning of the European Union

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I – Introduction

“Let us have no illusions: [...] Agencies may indeed be needed to give the Union bodies and authorities of the kind that exist in all systems today, and to allow the Commission better to perform its executive role without excessive bureaucratic burdens. But this must be done by maintaining the logic of the Community system. Those agencies must operate under the authority of the Commission – which is answerable to you [the European Parliament] for their actions.”

(Address by Mr Prodi to the European Parliament, 3 October 2000)¹

The creation of the first European agencies² dates back to the mid-1970s, when the European Community and, in particular, the European Commission responded to the growing need to reduce the regulatory’s workload and to provide for the co-ordination of the various bodies at EC level.³ Yet, since the late 1980s and early 1990s, the European Union (EU) experienced a dramatic increase, a ‘mushrooming’, in the number of such agencies.⁴ The emergence of this frequently called ‘second generation’ of European agencies can be retraced to the launch of the Single Market Programme in 1987 and the resulting, increased demand for technical and scientific advice, as well as the co-ordination of new tasks and policy areas attributed to the Community.⁵ Following this ‘second generation’ of European agencies, recent years have witnessed a further wave in the creation of new agencies. The most recent example is the European Chemicals Agency (ECHA), which became fully operational only two month ago, on 1 June 2008.

Indicated by the excerpt of Romano Prodi’s speech above, the delegation of power to more and more agencies did not take place without critical voices and resistance – from outside the EC institutions, but also from within. Like Prodi’s speech, most of these criticisms have focused on concerns related to the agencies’ control and accountability. Already in 1958 did the momentous *Meroni* rulings⁶ of the European Court of Justice (ECJ) introduce the so-called ‘anti-delegation doctrine’. In these judgments, the ECJ constrained the delegation of power from EU institutions to subordinate bodies by stating that only “clearly defined executive powers [...] which can be subject to strict review” could be

¹ Prodi, R. (2000) *Address by Mr Prodi to the European Parliament – The Danger of Fragmentation*, Bulletin EU 10-2000, 3 October 2000, available at: <<http://europa.eu/bulletin/en/200010/p000411.htm>>.

² The European Centre for the Development of Vocational Training and the Foundation for the Improvement of Living and Working Conditions.

³ Vos, E. (2003) ‘Agencies and the European Union’, in: L. Verhey and T. Zwart (eds.), *Agencies in European and Comparative Law*, Antwerp: Intersentia Publishing, at p. 113ff.

⁴ Dehousse, R. (2002) *Misfits: EU Law and the Transformation of European Governance*, Jean Monnet Working Paper 2/02, at p. 8.

⁵ European Commission (2008) *History of Community Agencies*, available at: <http://europa.eu/agencies/community_agencies/history/index_en.htm>.

transferred.⁷ Most importantly, ‘discretionary powers’ were under no circumstances to be delegated to bodies other than the EC institutions.⁸ The Court’s main fear behind these judgments was the disturbance of the ‘institutional balance’ which supposedly underlies the European Union’s structure. The Court argued that only the preservation of this institutional balance would allow the powers of every institution to be traced back to a democratically elected Parliament, herewith guaranteeing the EU’s democratic legitimacy.⁹ This concern is shared by Romano Prodi when referring to the need of “maintaining the logic of the Community system”.

Adhering to the anti-delegation doctrine, the EC institutions have up to now largely avoided the delegation of actual decision-making powers to European agencies.¹⁰ Until recently, not more than three out of 23 Community Agencies were granted limited, and most importantly only non-discretionary, decision-making powers: the Office for Harmonisation in the Internal Market (OHIM), the Community Plant Variety Office (CPVO) and the European Aviation Safety Agency (EASA).¹¹ Whereas OHIM and CPVO were already created in 1994, thus, shortly after the completion of single European market programme in 1992, no further agency entrusted with decision-making power was established until 2002 (marking EASA’s start-date of operating). In addition, the two important regulatory agencies, the European Food Safety Authority (EFSA)¹² and the European Medicines Agencies (EMA),¹³ created in 2003 and reformed in 2004 respectively, were refused any independent rule-making powers.

⁶ Case 9/56 *Meroni and Co., Industrie Metallurgiche S.p.A. v. Highly Authority* [1957-58] ECR 133 and Case 10/56 *Meroni and Co., Industrie Metallurgiche S.p.A. v. Highly Authority* [1957-58] ECR 157.

⁷ Curtin, D. (2007) ‘Holding (Quasi-) Autonomous EU Administrative Actors to Public Account’, *European Law Journal* 13(4), at p. 527.

⁸ Vos, E. (2000) ‘Reforming the European Commission: What Role to Play for EU Agencies?’, *Common Market Law Review* 37, at p. 1123.

⁹ *Ibid.*

¹⁰ Dehousse 2002, loc. cit. n. 4, at p. 13; van Ooik, R. (2005) ‘The Growing Importance of Agencies in the EU: Shifting Governance and the Institutional Balance’, in: Curtin, D. and Wessel, R.A. (eds.), *Good governance and the European Union: reflections on concepts, institutions and substance*, Antwerp: Intersentia, at p. 151.

¹¹ OHIM was established by Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (consolidated version), available at: <<http://oami.europa.eu/EN/mark/aspects/reg.htm>> (hereafter: “Trade Mark Regulation”); CPVO was established by Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1994] *OJL* 227; and EASA was established by Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency [2002] *OJL* 240 (hereafter: “EASA Regulation”). See also Vos 2003, loc. cit. n. 3, at p. 121.

¹² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] *OJL* 31 (hereafter: “General Food Law”).

¹³ Established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] *OJL* 136 (hereafter: “EMA Regulation”).

Against this background did the European Chemicals Agency commence its work in Helsinki on 1 January 2008, where its main task is the management and administration of the new European chemicals policy, coined by the so-called REACH system (Registration, Evaluation and Authorisation of Chemicals).¹⁴ Recalling the trend of ‘mushrooming’ of European agencies in the last two decades, the creation of a ‘further’ agency is not particularly surprising. Yet, in its very recent Communication, published on 11 March 2008, the Commission classifies the European Chemicals Agency as a regulatory agency able to adopt “individual decisions which are legally binding on third parties”.¹⁵ Being aware of the concerns of accountability and control of European agencies and the Union’s (continued) adherence to the *Meroni* doctrine, the granting of decision-making powers has to be seen as exceptional, definitively deserving particular attention.

Therefore, the focus of this Thesis will be on the European Chemicals Agency and, in particular, on this Agency’s decision-making powers: to what extent is the delegation of power to ECHA still compatible with the *Meroni* conditions? And, what mechanisms have been inserted to hold ECHA accountable for its decisions and to control its activities?

Approaching these questions, this paper will, after a more general overview of European agencies, on the one hand, and the EU chemicals policy, on the other, introduce the new European Chemicals Agency – its organisational structure, its tasks and, of course, the nature of its decision-making powers. In doing so, a comparative method will be used, contrasting the Chemicals Agency with relevant existing agencies whose compatibility with the old-established *Meroni* conditions has long been accepted. Hereby, the three existent Community agencies with decision-making powers and the two prominent regulatory agencies EMEA and EFSA will serve as the basis of comparison. Although EFSA and EMEA do not dispose of decision-making powers, a comparison to them is still valuable as it will be shown that they are engaged in tasks resembling those of ECHA. Subsequently, the second part of the analysis will turn to the important questions of control and accountability. Here, it will be examined, again in comparison to the aforementioned existent agencies, which supervision mechanisms have been inserted in the Chemicals Agency’s design.

¹⁴ The ECHA and the REACH system were established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, [2006] OJ L396 (hereafter: “REACH Regulation”).

¹⁵ European Commission, *European Agencies – The Way Forward*, Communication from the Commission to the European Parliament and the Council, COM(2008) 135 final, 11 March 2008, Brussels.

II – Agencies, Delegation and the Anti-Delegation Doctrine

The first Chapter of this Thesis aims to impart a solid background knowledge of the current Agency debate. Hereby, a threefold aim will be pursued: firstly, the Chapter strives to clarify not only what a European agency actually is, but also why it emerged at European level. Secondly, the theoretical framework to the delegation of decision-making powers to agents, in general, and to European agencies, in particular, will be introduced. In this context, problems in the delegation of powers, particularly at European level, and the anti-delegation doctrine of the European Court of Justice, based on the famous *Meroni* judgments of 1958, will be discussed. Finally, the Chapter will provide an overview of the different ‘means’ of how to hold European agencies accountable.

II.1 Agencies, Agencies, Agencies

On 3 June 2008, the European Chemicals Agency (ECHA) was formally inaugurated by European Commission President José Manuel Barroso¹⁶ in Helsinki, and is therewith not only the most recent, but already the 24th entrant into the ‘family’ of European Community agencies.¹⁷ The trend of ‘mushrooming’, as the increase in European agencies was termed by scholars like Renaud Dehousse, has been attributed mainly to the launch of the Single European Market Programme in 1987.¹⁸ The increasing market integration implied a transfer of powers from national to EC level, thus necessitating the delegation of more and more responsibilities to the Commission.¹⁹ The Commission, in turn, recognised this unique opportunity to expand its regulatory activities, but was ill-prepared to perform the newly acquired tasks since it lacked the respective resources – in financial and human terms – as well as the required expertise.²⁰ An expansion of the Commission itself was not to be anticipated, due to the fierce and persistent opposition of several eurosceptic Member States, which felt confirmed when the BSE crisis and several corruption scandals revealed dramatic shortcomings in the Commission’s regulatory capacity.²¹

¹⁶ European Commission (2008) *Enterprise & Industry newsroom for the REACH sector*, available at: <http://ec.europa.eu/enterprise/newsroom/cf/newsbytheme.cfm?displayType=consultations&tpa_id=167>.

¹⁷ European Commission (2008) *Community Agencies*, available at: <http://europa.eu/agencies/community_agencies/index_en.htm>.

¹⁸ Dehousse 2002, loc. cit. n. 4, at p. 8.

¹⁹ Vos 2000, loc. cit. n. 3, at p. 1114.

²⁰ cf. Williams, G. (2005) ‘Monomaniacs or Schizophrenics?: Responsible Governance and the EU’s Independent Agencies’, *Political Studies* 53, at p. 88; Kelemen, R. D. (2002) ‘The Politic of ‘Eurocratic’ Structure and the New European Agencies’, *West European Politics* 25(4), at p. 95.

²¹ Keleman 2002, loc. cit. n. 20, at p. 100; Vos 2000, loc. cit. n. 3, at p. 1115.

The solution to the ‘regulatory problem’ was seen in the creation of agencies. In the 2000 White Paper ‘Reforming the Commission’, the Commission introduced the “policy of externalisation”,²² hereby referring to the decentralisation of executive and regulatory tasks to independent agencies. At large, agencies are considered (and hoped) to provide the urgently needed scientific and technical expertise and help to reduce the Commission’s workload. Furthermore, and especially in the light of recent food crises and corruption scandals, agencies are expected to screen technical regulatory tasks from political pressure and, thus, enhance transparency, credibility and accountability through the clarification of competences.²³ In ECHA’s inauguration speech, Barroso justified the agencies’ existence as follows:

“[t]he Commission depends fundamentally on the Agencies to ensure effective execution of their tasks and to advise the Commission on many sensitive topics. A report of the French Senate in October 2005 noted that the European Union had created more regulatory agencies in the previous 50 months than it had during the first 50 years of European integration, and wondered whether this was a cause for celebration, satisfaction or worry. But rather than view the proliferation of agencies as a dilution of the executive function of the Commission, as some fear, I prefer to consider the agencies as useful tools, where necessary, to help us to perform that executive function more efficiently and with more impact. The use of agencies has helped us to ensure that public policy retains continuity, credibility and visibility, and that we, as the Commission, fulfil our obligation to protect the general interest of the European Union.”²⁴

Reading Barroso’s speech, agencies appear to be the miraculous cure to virtually all the Commission’s problems it has experienced in the last two decades. Such commendation certainly deserves closer consideration – thus, what *are* European Agencies? First and foremost, European Agencies have been established under the EU Treaty (second and third pillar) as well as under the EC Treaty (first pillar); yet, within the scope of this Thesis, the focus will exclusively be on European Community Agencies, i.e. those created under the first EC pillar. Unfortunately, up to now, the European Community has not yet adopted an official definition of an ‘Agency’,²⁵ however, its website provides for a description of a ‘Community Agency’ as

²² European Commission, *Reforming the Commission*, White Paper, COM(2000) 200 final, 5 March 2000, Brussels, p. 10.

²³ Majone, G. (2002) ‘Delegation of Regulatory Powers in a Mixed Polity’, *European Law Journal* 8(3), at p. 329; Vos 2000, loc. cit. n. 8, at p. 1119; Geradin D. and Petit N. (2004) ‘The Development of Agencies at EU and National Levels: Conceptual Analysis and Proposals for Reform’, Jean Monnet Working Paper 01/04 (New York: New York University School of Law).

²⁴ Barroso, M. J. (2008) *European Chemicals Agency: Turning REACH into Reality*, Inauguration of the European Chemicals Agency, SPEECH 08/298, 3 June 2008, Helsinki, at p. 3.

²⁵ Van Ooik 2007, loc. cit. n. 10, at p. 134.

“a body governed by European public law; it is distinct from the Community Institutions (Council, Parliament, Commission, etc.) and has its own legal personality. It is set up by an act of secondary legislation in order to accomplish a very specific technical, scientific or managerial task, in the framework of the European Union’s ‘first pillar’.”²⁶

This rather broad definition contains a few elements which are shared by all Community agencies. First, agencies are *created by regulation*, depending on the legal basis, either by the Council alone or in co-operation with the European Parliament (EP). A major problem has been and still is that neither the constituent treaties nor the Lisbon Treaty provide for a specific legal basis enabling the establishment of agencies.²⁷ So far, the creation of such a legal basis has been refused; it has been argued that its insertion would disturb the institutional balance through the creation of conflicting centres of power (cf. Prodi’s speech). Circumventing the lack of a legal basis, the first European agencies were created with the help of Article 308 EC, a provision generally used to fill gaps where the Treaty does not provide for a specific legal basis for the achievement of one of the EC’s objectives listed in Article 3 EC. However, Article 308 EC only allows for very little involvement of the EP, as merely its consultation is required. The situation gradually changed with the European Environment Agency (EEA), the first agency to be based not on Article 308 EC, but on a specific legal basis, namely Article 175 EC on environmental protection.²⁸ Later agencies were also based on Article 95 EC, provided that the agency’s main purpose referred to the harmonisation of the internal market. Important is that Article 175 and 95 EC allow for a much greater involvement of the EP, as the co-decision procedure is applicable, which gives the EP veto-power and the status of a co-legislator.²⁹

Secondly, agencies are *non-majoritarian* institutions, meaning that they are engaged in public functions but enjoy some degree of independence from elected politicians.³⁰ Questions of legitimacy and accountability arise in this respect, however, those will be dealt with in the course of this paper. Furthermore, agencies are established for *specified, normally highly technical tasks* which are clearly defined in their constituent regulations.³¹

²⁶ European Commission (2008) *Agencies*, available at: <http://europa.eu/agencies/index_en.htm>.

²⁷ Curtin 2007, loc. cit. n. 7, at p. 527.

²⁸ Vos 2000, loc. cit. n. 8, at p. 1121.

²⁹ Cf. co-decision procedure, Lenaerts, K. and van Nuffel, P. (2005) *Constitutional Law of the European Union*, 2nd Edition (London: Sweet & Maxwell), at pp. 592-598.

³⁰ Curtin 2007, loc. cit. n. 7, at p. 527.

³¹ Flinders, M. (2004) ‘Distributed Public Governance in the European Union’, *Journal of European Public Policy* 11(3), at p. 524.

Thirdly, Community agencies enjoy some degree of organisational and financial *autonomy* from the Commission.³² Finally, all agencies have *legal personality*.³³

This rather broad description to be found on the EU's website can be explained by the fact that even though certain similarities can be discerned, the existing agencies' internal structure, responsibilities and powers differ significantly. This is mainly because the present agencies were not established according to a common approach but on an *ad hoc* basis as a reaction to specific, often pressing circumstances.³⁴ Concerned about issues of accountability and legitimacy, the Commission has criticised the absence of such a common approach.³⁵ Already in 2005, it had proposed an inter-institutional agreement providing for a common operating framework for all regulatory agencies established under the EC Treaty, including clear conditions concerning their operation, supervision and creation.³⁶ So far, however, the Council could not agree on the adoption of such an agreement.

Various attempts of classification of the existing agencies were made by various scholars.³⁷ Yet, there is a general agreement that a functional typology is most appropriate:³⁸ hereafter, agencies may be classified into those entrusted with information, managerial or regulatory functions. Information agencies are broadly engaged in the gathering, analysis and dissemination of information relating to a particular policy area.³⁹ Management agencies are responsible for the implementation of Community programmes, and regulatory agencies are involved in the regulation of social and economic policies.⁴⁰

A relatively broad but clear cut classification was adopted by the Commission in its Communication on the Operating Framework for the European Regulatory Agencies of 2005.⁴¹ Here, it distinguished between two main categories of agencies: executive and regulatory ones. Whereas executive agencies are concerned with "purely managerial tasks",

³² Ibid., at p. 524.

³³ van Ooik 2007, loc. cit. n. 10, at p. 132.

³⁴ Geradin and Petit 2004, loc. cit. n. 23, at p. 39.

³⁵ European Commission, *The operating framework for the European Regulatory Agencies*, Communication from the Commission, COM(2002) 718 final, 11 December 2002, Brussels, at p. 6.

³⁶ Ibid.

³⁷ Geradin and Petit 2004, loc. cit. n. 23, at p. 47; Chiti, E. (2000) 'The Emergence of a Community Administration: The Case of European Agencies', *CML Review* 37, at p. 315-317; Griller S. and Orator A. (2008a) 'Mapping the Jungle: A Legal Attempt to Classify European Agencies', *NEWGOV Policy Brief* No. 22.

³⁸ cf. van Ooik 2005, loc. cit. n. 10, at p. 139-44; Vos 2003, loc. cit. n. 3, at p. 119; Dehousse 2002, loc. cit. n. 4, at p. 9.

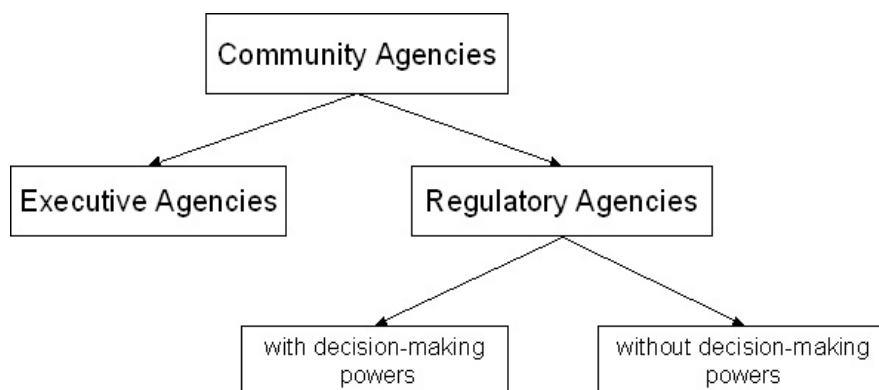
³⁹ Vos 2003, loc. cit. n. 3, at p. 119.

⁴⁰ Ibid.

⁴¹ European Commission, *The operating framework for the European Regulatory Agencies*, see *supra* n. 35, at p. 6.

are established for a fixed period of time only⁴² and are mainly responsible for the implementation of specific programmes, regulatory agencies, on the contrary, are “actively involved in the executive function by enacting instruments which help to regulate a specific sector”⁴³ (cf. Figure 1). Within the latter category, the Commission further differentiates between those regulatory agencies having decision-making powers, i.e. those having the ability to adopt measures which are legally binding on third parties, and those agencies that are not granted independent powers vis-à-vis third parties. Confusingly, the latter category within regulatory agencies was originally also referred to as ‘executive agencies’.⁴⁴ This inconsistency has, however, been resolved by the Commission. Since ECHA is involved in the regulation of the European chemicals policy, it is, beyond doubt, a regulatory agency. Therefore, the focus will be on regulatory rather than on executive agencies.

Figure 1:



In order to “improve the way rules are applied and enforced across the Union”, the Commission advocated the creation of further regulatory agencies in the White Paper on European Governance.⁴⁵ Nevertheless, as it was alluded to in the introduction and will further be discussed below, the delegation of powers to agencies has been subject to considerable criticism and concern.

II.2 The Problem of Delegation

According to a definition by Deirdre Curtin, delegation has to be seen as “an authoritative decision, formalised as a matter of public law that [...] transfers policy making authority

⁴² See European Commission (2008) *Executive Agencies*, available at: http://europa.eu/agencies/executive_agencies/index_en.htm.

⁴³ See *supra* n. 35, pp. 3-4.

⁴⁴ Cf. Geradin and Petit 2004, loc. cit. n. 23, at p. 46.

⁴⁵ European Commission, *White Paper on European Governance*, COM(2001) 428 final, 25 July 2001, Brussels, at p. 24.

away from the established, representative organs [...] to [...] a public non-majoritarian institution”.⁴⁶ The principal-agent framework is a well-known and useful tool to illustrate the process of delegation: a principal transfers certain powers and tasks to an agent, who is expected to act on the principal’s behalf.⁴⁷ The principal-agent framework originated in the context of national democracies, where the parliament (i.e. the legislature) acts as the principal which is directly elected by the people and which delegates powers to an administrative body, the agent. One major risk that might arise in the exercise of delegation is the ‘bureaucratic drift’.⁴⁸ A bureaucratic drift occurs where the agent starts to pursue a policy agenda which is different in nature from that of its principal; in order to prevent the occurrence of such a drift, the principal normally inserts mechanisms to control the agent.⁴⁹ In the national context, the framework works as follows: a direct chain of delegation between principal and agent emerges (voter-parliament-administrative body), through which the agent is controlled by, i.e. can be held accountable to, the principal.⁵⁰

Although it is possible to apply the framework in the EU context, to do so has proven to be much more complex than at national level. First and foremost, it is in most cases not the EU legislature that transfers power, but the European Commission, which is primarily engaged in executive functions. Eventually, even though agencies are, as explained above, formally established by the Council (potentially with the EP as co-legislator), it is predominantly the Commission’s tasks that are delegated. Secondly, not all the tasks delegated must have been previously carried out by the Commission, but may have been those of Member States. Consequently, multiple principals may be involved in the setting up of European agencies, namely the Council, potentially the EP, the Commission, and in some instances also the national Parliaments.⁵¹ Accordingly, and contrary to the national context, it is hardly possible to identify clear chains of delegation at EU level. Critics, like Romano Prodi in his speech cited in the introduction, assert that the creation of agencies has led to an increasing fragmentation of tasks, making the decision-making process more complex and less transparent, which has resulted in an “erosion of accountability” at European level.⁵² Putting this criticism in the context of the principal-

⁴⁶ Curtin, D. (2005) ‘Delegation to EU Non-Majoritarian Agencies and Emerging Practices of Public Accountability’, in: D. Geradin, R. Muñoz (eds.), *Regulation through agencies in the EU. A new paradigm of European governance* (Cheltenham: Edward Elgar), at p. 90.

⁴⁷ Curtin 2007, loc. cit. n. 7, at p. 525.

⁴⁸ Kelemen 2002, loc. cit. n. 20, at p. 96.

⁴⁹ Ibid.

⁵⁰ Curtin 2007, loc. cit. n. 7, at p. 525.

⁵¹ Ibid., at pp. 528-9.

⁵² See Vos 2000, loc. cit. n. 8, at p. 1120.

agent framework, one can argue that the complex net of chains of delegation at EU level makes it more difficult for the principal(s) to control its/their agents.

Furthermore, the delegation of powers has evoked criticisms regarding the agencies' legality and independence. On the one hand, criticism has focused on the agencies' lack of a specific legal basis, thus raising questions about those bodies' legality (see discussion above).⁵³ Yet, there is no prospect of reform in the near future, as also the Lisbon Treaty will not provide for a legal basis for agencies. The main reason therefore, namely the preservation of the institutional balance, has been explained above. On the other hand, critics have warned against the so-called "regulatory capture".⁵⁴ The regulatory capture describes a situation where the regulatory body comes too close to the regulatees' interests, thereupon compromising its independence.⁵⁵ European agencies are under risk not only of being 'captured' by powerful economic interests of the European industry, but also by national regulatory authorities (NRAs).⁵⁶ Having outlined the (potential) issues related to the delegation of power, how did the European Community respond to those challenges?

II.3 Anti-Delegation

The difficulty inherent in delegation, particularly at the EU level, has been dealt with by the European Court of Justice (ECJ) as early as in 1958 in the context of the European Coal and Steel Community (ECSC). In its *Meroni* judgments⁵⁷, the Court established the far-reaching 'anti-delegation doctrine', expressly and considerably limiting the institutions' ability to delegate power to administrative bodies.⁵⁸ As it has been briefly described above, the Court justified its decision by reference to the 'institutional balance', a balance of power arguably underlying the EC's institutional structure (Commission, EP, Council),⁵⁹ following the Court, the preservation of this balance is necessary for the Union's democratic legitimacy, which requires that "the powers of any rule-making body ultimately should be traced back to the authority of a democratically elected parliament" (cf. the principle-agent framework).⁶⁰ Accordingly, the Court established a set of restrictive criteria that have to precede any act of delegation: (i) the delegation of discretionary power is strictly

⁵³ *Ibid.*, at p. 1119.

⁵⁴ Flinders 2004, loc. cit. n. 31, at p. 538.

⁵⁵ *Ibid.*

⁵⁶ Williams 2005, loc. cit. n. 20, at p. 90.

⁵⁷ *Meroni* Cases, see *supra* n. 6.

⁵⁸ Vos 2000, loc. cit. n. 8, at p. 1123.

⁵⁹ Lenaerts, K. And Verhoeven, A. (2002) 'Institutional Balance as a Guarantee for Democracy in EU Governance', in: Joerges, C., Dehousse, R. (eds.), *Good Governance in Europe's Integrated Market* (Oxford, MA: Oxford University Press), at p. 37.

⁶⁰ *Ibid.*

prohibited;⁶¹ (ii) only clearly defined executive powers may be delegated;⁶² (iii) the delegating institution cannot transfer broader powers than it received itself under the Treaty,⁶³ and; (iv) the delegation of power must be subject to the stringent supervision of the institutions of the Community.⁶⁴

Many scholars have criticised a restrictive interpretation of the *Meroni* doctrine.⁶⁵ On the one hand, because the *Meroni* case law has been established 50 years ago – one may call it “prehistoric” – and did not even develop within the framework of the EC Treaty.⁶⁶ On the other hand, scholars, like Lenaerts and Verhoeven, assert that the strict adherence to the institutional balance has led to the emergence of a gap “between the formal constitution and the way the European Union really functions”.⁶⁷ According to them, institutional elements in the Community’s structure, such as European agencies, which have no specific legal basis in the Treaties (to do so would lead to conflicts with the institutional balance) and are therefore founded on rather doubtful Treaty provisions, pieces of case-law and secondary EC law, would operate in a “constitutional twilight zone”.⁶⁸ Similarly, Dehousse describes the insistence on the anti-delegation doctrine as “a façade to hide a reality that is deemed to be unacceptable”.⁶⁹ Instead of enhancing the EU’s legitimacy, the resulting, complex and semi-legal net of legislation would raise new questions of accountability and transparency.

Despite these criticisms, anti-delegation remains the official doctrine or, as Griller and Orator call it, “good law”.⁷⁰ In 2005, the ECJ confirmed in its *Alliance for Natural Health* case⁷¹ that:

“[...] when the Community legislature wishes to delegate its power to amend aspects of the legislative act at issue, it must ensure that that power is clearly defined and that the exercise of the power is subject to strict review in the light of objective criteria.”

⁶¹ *Meroni* Cases, see *supra* n. 6, at para. 152.

⁶² *Ibid.*

⁶³ *Ibid.*, at para. 150.

⁶⁴ *Ibid.*, at para. 152.

⁶⁵ Cf. van Ooik 2005, loc. cit. n. 10, at p. 150; Lenaerts and Verhoeven 2002, loc. cit. n. 59; Everson M. (2005) ‘Good Governance and European Agencies: the Balance’, in: D. Geradin (ed.), *Which Regulatory Authorities in the EU?* (Cheltenham: Edward Elgar).

⁶⁶ van Ooik 2007, loc. cit. n. 10, at p. 150.

⁶⁷ Lenaerts and Verhoeven 2002, loc. cit. n. 59, at p. 48.

⁶⁸ *Ibid.*

⁶⁹ Dehousse 2002, loc. cit. n. 4, at p. 17.

⁷⁰ Cf. Majone 2002, loc. cit. n. 23, at p. 337; Griller S. and Orator A. (2008b) ‘*Meroni* Revisited: Empowering European Agencies Between Efficiency and Legitimacy’, *NEWGOV*, Reference Number 04/D40, available at: <http://www.eu-newgov.org/ClusterOne/deliverables_detail.asp?Cluster1_Code=3>, at p. 8; van Ooik 2007, loc. cit. n. 10, at p. 150. See also Dehousse 2002, loc. cit. n. 4, at p. 14.

⁷¹ Joined Cases C-154/04 and C-155/04 *The Queen, on the application of Alliance for Natural Health and Others v. Secretary of State for Health and National Assembly for Wales* [2005] ECR I-06451, at para. 90.

Accordingly, even though the White Paper on European Governance recognised the need for the creation of further regulatory agencies at European level (cf. above), strict conditions therefore are listed; indeed, a comparison reveals that the conditions listed in the 2001 White Paper broadly correspond to the *Meroni* criteria of 1958.⁷² Implementing the *Meroni* conditions, the White Paper further stipulates that “Agencies cannot be granted decision-making power in areas in which they would have to arbitrate between conflicting public interests, exercise political discretion or carry out complex economic assessments”;⁷³ it is assumed that such a decision would be ‘discretionary’ in nature.⁷⁴ Consequently, the *Meroni* doctrine still poses a serious obstacle to the creation of further agencies at European level.⁷⁵

In order to adhere to this still valid doctrine, the delegation of discretionary power to agencies has so far been refused.⁷⁶ The most prominent regulatory agencies, the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA), are denied any possibility to take decisions on their own; instead, they submit their (scientific) opinions to the Commission, which eventually adopts them as draft decisions under the appropriate comitology procedure.⁷⁷ Thus, the actual decision-making power stays completely with the Commission. Until recently, only three Community agencies were granted limited decision-making powers: the Office for Harmonisation in the Internal Market (OHIM), the Community Plant Variety Office (CPVO), and the European Aviation Safety Agency (EASA).⁷⁸ Their authorisation to take decisions has been restricted to the implementation of EC programmes, the registration of trademarks and the issuing of certificates.⁷⁹

The previously identified risk of a ‘bureaucratic drift’ made clear that mechanisms to control agencies are important – independent of whether they have been granted decision-making powers or not. Taking EMA or EFSA as an example, even though they are not able to adopt decisions themselves, their opinions are of high relevance as they are, in most cases, accepted by the Commission without further scrutiny.⁸⁰ Yet, it is also obvious that the more an agency is allowed to decide independently, the higher is the necessity to insert

⁷² Cf. European Commission, *White Paper on European Governance*, see *supra* n. 45, at p. 24. This statement was confirmed in the Commission Communication on an operating framework for the European Regulatory Agencies published in 2005, see *supra* n. 35, at p. 11.

⁷³ *Ibid.*

⁷⁴ Dehousse 2002, loc. cit. n. 4, at p. 13.

⁷⁵ van Ooik 2007, loc. cit. n. 10, at p. 150.

⁷⁶ Dehousse 2002, loc. cit. n. 4, at p. 13.

⁷⁷ *Ibid.*

⁷⁸ See *supra* n. 35, at p. 7.

⁷⁹ Vos 2003, loc. cit. n. 3, at p. 121.

⁸⁰ Gehring, T. and Krapohl, S. (2007) ‘Supranational regulatory agencies between independence and control: the EMA and the authorisation of pharmaceuticals in the European Single Market’, *Journal of European Public Policy* 14(2), at p. 209.

control and supervision mechanisms.⁸¹ In order to comply with the *Meroni* doctrine, it is essential not only that the non-discretionary decision-making powers are clearly defined in the constituent regulations of the agencies, but also that appropriate supervision is provided for which enables the EC institutions (i.e. the principals) to hold the agencies (i.e. their agents) accountable for their activities.

II.4 Accountability and Control

European agencies have to be regarded as part of the emerging multi-level structure of governance within the European Union, which has been triggered by the dispersal of authority from national level to supranational and subnational actors.⁸² Apparently, agencies cannot be considered as “traditional institutions of government”, as they developed outside the national system of parliamentary democracy.⁸³ The multi-level structure of governance has, as it became clear above, led to the emergence of multiple chains of delegation at European level, which, in turn, resulted in the proliferation of accountability relations.⁸⁴ Furthermore, this multi-level character of governance implies that European organs, including agencies, may be controlled not only by the EC institutions, but also by national forums.⁸⁵ Generally, however, the shift of power to multi-level governance has not been matched with a concurrent creation of adequate regimes of accountability; not for nothing has the EU’s “democratic deficit” dominated the literature on European governance since the 1970s.⁸⁶

It was in the context of this multi-level structure of European governance that Mark Bovens recognised the importance of further forms of accountability, complementary to “traditional accountability arrangements” used in national democracies.⁸⁷ At large, means to hold agents accountable may operate on an *ex ante* (in advance) or on an *ex post* (retroactive) basis.⁸⁸ This Section will provide an overview of the most important forms of accountability.

Yet, before starting this discussion, it appears necessary to clarify the relation and the meaning of the two concepts of accountability and control as used in this paper; so far,

⁸¹ Cf. Griller and Orator 2008b, loc. cit. n. 70, at p. 9.

⁸² Flinders 2004, loc. cit. n. 31, at p. 532; Hooghe, L. and Marks G. (2001) ‘Types of Multi-Level Governance’, *European Integration Online Papers* 5, at p. 1, available at: <<http://eiop.or.at/eiop/texte/2001-011a.htm>>.

⁸³ Flinders 2004, loc. cit. n. 31, at p. 533.

⁸⁴ Curtin 2005, loc. cit. n. 46.

⁸⁵ Bovens, M. (2007) ‘New Forms of Accountability and EU-Governance’, *Comparative European Politics* 5, at p. 112.

⁸⁶ *Ibid.*, at p. 104.

⁸⁷ *Ibid.*, at p. 105.

the paper has used the two terms almost interchangeably. According to the Oxford English Dictionary, *accountable* means to be “required or expected to justify actions or decisions”.⁸⁹ According to this literal meaning of the word, Bovens adopted a narrow definition of accountability, describing it “as a relationship between an actor and a forum, in which the actor has an obligation to explain and to justify his or her conduct”.⁹⁰ *Control*, on the other hand, means “the power to influence people’s behaviour or the course of events”.⁹¹ The concept of control is thus broader than that of accountability as it implies that a forum can exert power over the actor, and not only that the actor has to justify itself.⁹² Therefore, it would be wrong to equate accountability with control.

The purpose of this research is, however, to identify supervisory mechanism that have been inserted by the principals to avoid the ‘drifting away’ of their agents, the agencies. In this context, the agents’ obligation to justify themselves (accountability) and the principals’ possibility to exert power over the agent (control) are of equal relevance. Consequently, when describing the different forms of accountability, also possibilities of the agencies’ control will be examined.

II.4.1 Traditional Accountability Arrangements

As “traditional accountability arrangements” in western democracies Bovens identifies those forms of accountability which follow the principal-agent relationship, most notably *democratic accountability*.⁹³ As described above, in the classical principal-agent relationship it is the voter who delegates power to the national Parliament (the principal) which, in turn, delegates power to administrative actors (the agents), such as agencies. The mechanism of democratic accountability operates in the directly opposite direction: the administrative actor has to justify its conduct to the national Parliament, which in turn is answerable to the voter.⁹⁴ At the same time, the principal, i.e. the national Parliament, inserts mechanisms to control the agent in order to prevent the bureaucratic drift.⁹⁵ With respect to the European level and its multiple chains of delegation, however, this form of accountability is of limited importance: at European level the voter only directly delegates power to one institution, namely to the European Parliament. Yet, as it became clear above,

⁸⁸ Curtin 2005, loc. cit. n. 46, at p. 98.

⁸⁹ AskOxford.com (2008) *accountable*, available at: <http://www.askoxford.com/concise_oed/accountable?view=uk>.

⁹⁰ Bovens 2007, loc. cit. n. 85, at p. 107.

⁹¹ AskOxford.com (2008) *control*, available at: <http://www.askoxford.com/concise_oed/control?view=uk>.

⁹² Bovens 2007, loc. cit. n. 85, at p. 108.

⁹³ E.g., Geradin and Petit 2004, loc. cit. n. 23, at p. 53.

⁹⁴ Bovens 2007, loc. cit. n. 85, at p. 110.

the Parliament neither always acts as the principal nor does it provide for extensive supervision powers.⁹⁶ For democratic accountability to work properly, a direct chain of delegation is needed.⁹⁷

II.4.2 Other Forms of Accountability

Recognising this limited relevance of traditional accountability regimes at European level, additional forms of accountability are required in order for the (multiple) principal(s) to ensure that their agents, the agencies, do not ‘drift’ away. Those will be dealt with in turn.

Accountability through Legislation

The most obvious *ex ante* form of accountability is the clear definition of the agency’s responsibilities, tasks and reporting requirements in its constituent regulation.⁹⁸ The more detailed the agencies’ structure, powers and functions are defined in advance, the easier is their control. This form of accountability will be referred to as accountability through legislation.

Member State Accountability

As said above, the multi-level structure of governance at European level implies that not only European institutions, but also the Member States themselves can hold European actors, the agencies, to account.⁹⁹ Therefore, Member State control often plays an important part in the supervision of agencies. As it will be seen below, in the classical structure of a regulatory agency, its Management Board is composed of Member State representatives, allowing them to oversee the agency’s activities.¹⁰⁰

Financial Accountability

Different to the aforementioned accountability through legislation, financial but also judicial oversight mechanisms work on an *ex post* basis.¹⁰¹ The principal mechanisms for ensuring financial accountability at European level include, first of all, the budgetary power enjoyed by the EP over non-compulsory expenditures (for agencies dependent on the Community

⁹⁵ See *supra* Section II.2.

⁹⁶ Bovens 2007, loc. cit. n. 85.

⁹⁷ Flinders 2004, loc. cit. n. 31; Cf. Theory of Representative Democracy.

⁹⁸ Curtin 2005, loc. cit. n. 46, at pp. 98-105.

⁹⁹ *Ibid.*, at p. 112.

¹⁰⁰ Cf. below Chapter IV.1.

¹⁰¹ Geradin and Petit 2004, loc. cit. n. 23, at pp. 51-52.

budget); furthermore, many agencies are subject to the supervision of the Court of Auditors, who is able to oversee the agencies' annual accounts pursuant to Article 248 EC.¹⁰² Finally, most agencies allow the European Anti-Fraud Office (OLAF) to conduct investigations in order to detect cases of fraud and corruption.¹⁰³

Judicial Accountability

Judicial accountability usually refers to the legal review of agencies' acts.¹⁰⁴ In principle, legally binding acts adopted by the EU institutions are challengeable before the European Court of Justice or the Court of First Instance under Article 230 EC (action for annulment). However, this Article does not (yet) include acts adopted by European Agencies. This 'gap' will be filled with the entering into force of the Lisbon Treaty since Article 263 TFEU will amend Article 230 EC so as to include a reference to European agencies. Meanwhile, most constituent regulations explicitly allow for challenges on the basis of Article 230 EC.¹⁰⁵

More problematic is the legal review of scientific opinions adopted, for example, by EMEA and EFSA, as they create no legal effects on third parties but are merely "preparatory acts" constituting the basis for a decision eventually taken by the Commission.¹⁰⁶ Because of their non-bindingness, it was established in the *Olivieri* case that agencies' opinions cannot be directly challenged before the Community Courts.¹⁰⁷ The CFI kept this position also in its more recent judgments: in the *FMC Chemicals v. EFSA* case, for example, it ruled that EFSA's scientific opinions may not as such be the subject to judicial review.¹⁰⁸ Nevertheless, in the *Artegodan* judgments of 2002, the CFI, later confirmed by the ECJ, held that scientific opinions prepared by EMEA's Committee for Proprietary Medicinal Products (CPMP) are "[n]onetheless extremely important so that any unlawfulness of that opinion must be regarded as a breach of essential procedural requirement rendering the Commission's decision unlawful".¹⁰⁹ This means that in case an opinion is "unlawful", not the opinion itself, but the Commission's decision based on that opinion might be judicially reviewed and, if necessary, annulled.

¹⁰² *Ibid.*, at p. 53.

¹⁰³ European Commission (2008) *OLAF – Our Objective*, available at: <http://ec.europa.eu/anti_fraud/index_en.html>.

¹⁰⁴ Geradin and Petit 2004, loc. cit. n. 23, at p. 51.

¹⁰⁵ *Ibid.*, at p. 51.

¹⁰⁶ Alemanno, A. (2007) *Science and EU Risk Regulation: The Role of Experts in Decision-Making and Judicial Review*, Paper presented at Young Researchers Workshop on Science and Law - Scientific Evidence in International and European Law, 31 May - 1 June 2007 Lecce, Italy: ISUFI), at p. 16.

¹⁰⁷ Case T-326/99 *Olivieri v. Commission* [2003] ECR II-6053.

¹⁰⁸ Cases T-311/06 RI, T-311/06 RII, T-312/06 R and T-313/06 R: Order of the President of the Court of First Instance of 1 March 2007 - *FMC Chemical and Others v. EFSA* [2007] C 95/86.

¹⁰⁹ Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 *Artegodan v.*

Yet, what are “unlawful” opinions? Scientific opinions naturally consist of a complex risk assessment conducted by experts. How could a judge evaluate the correctness of such a scientific assessment? Faced with this dilemma during the BSE crisis, the Court reacted by declaring that

“[...] since the Commission enjoys a wide measure of discretion, particularly as to the nature and extent of the measures which it adopts, the EC judicature must, when reviewing such measures, restrict itself to examining whether the exercise of such discretion is vitiated by a manifest error or a misuse of powers or whether the Commission did not clearly exceed the bounds of its discretion.”¹¹⁰

Eventually, only in cases of “manifest error or a misuse of power” would the Court interfere and annul a Commission’s decision because of the scientific assessment on which it is based; thus, the ECJ adopted a cautious approach to the review of acts based on scientific data.

The picture becomes even more complex when taking into account the *Thomae v. Commission* judgment of 2002.¹¹¹ In the aforesaid judgment, EMEA – even though not officially entrusted with decision-making powers – was able to reject an application by the Dr. Karl Thomae GmbH in which the applicant requested a variation of the terms of its marketing authorisation for a medicinal product that had been previously granted by the Commission in accordance with Article 5(4) of Regulation 542/95:

“[w]here the Agency is of the opinion that the application cannot be accepted, it shall send a notification to that effect to the holder of the marketing authorisation within the period referred to in paragraph 1, stating the objective grounds on which its opinion is based.”¹¹²

The Court accepted EMEA’s rejection of the application (in Article 5(4) referred to as an opinion) as a ‘decision’ which can be reviewed by the Community Courts. Because the Court found that the decision was based on a wrong interpretation of Community law, and was in addition to that not sufficiently reasoned, it annulled EMEA’s act.¹¹³ Thus, the Court demonstrated in this judgment that it might be willing to also review acts of Agencies which do not formally dispose of decision-making powers.

Commission [2002] ECR 4945, at para. 197.

¹¹⁰ Case C-157/96 *National Farmers’ Union and Others* [1998] ECR I-2211, para. 39.

¹¹¹ Case T-123/00 *Dr Karl Thomae GmbH v. Commission* [2002] ECR II-5193.

¹¹² Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93 [1995] OJL 55.

¹¹³ *Thomae v. Commission*, see *supra* n. 111, at para. 83.

Hence, it can be summed up that the judicial review of the Agencies' decisions is by no means standardised, but is dealt with on an *ad hoc* basis, depending on what is written down in each agency's constituent regulation.¹¹⁴ A particular problem emerges with respect to scientific opinions prepared by agencies; on the one hand, because they are not legally-binding, on the other, because judges lack the ability to assess the scientific data on which those opinions are naturally based. The result is an 'accountability gap' as agencies may not be held responsible for the contents of their opinions. Furthermore, the *Thomae v. Commission* case has shown that the Courts might be willing to also review certain acts of Agencies which do not formally possess decision-making powers. Certainly, this judgment further added to the already confusing judicial oversight of Agencies. Beyond doubt, the current judicial control of Agencies leaves room for improvement.

Social Accountability

Social accountability, as termed by Mark Bovens, refers to the agencies' accountability to civil society.¹¹⁵ This includes the participation of stakeholders and interested parties in the agencies' work and decision-making process, through public consultations, inclusion of stakeholders in Management Boards or external experts. One indispensable prerequisite for public participation is transparency.¹¹⁶ Without transparent procedures, the publication of information and the right of access to the agency's documents, participatory governance is impossible.¹¹⁷ Up to now, the relevant Treaty Article 255 EC, dealing with the right to access to documents, is not addressed to European Agencies, but is limited to the documents of Council, Commission and EP.¹¹⁸ To remedy this shortcoming, Regulation 1049/2001 on public access to EP, Council and Commission documents explicitly extends its application to European agencies.¹¹⁹ In addition, most agencies have adopted respective decisions or articles in their constituent regulations, providing for the access to their documents, and make extensive use of the internet as a platform for information exchange.¹²⁰

The opening up of the agencies' work to civil society, through transparent and clearly defined procedures, can be regarded as an indirect oversight mechanism (also

¹¹⁴ Cf. van Ooik 2007, loc. cit. n. 10, at p. 148, Nieto-Garrido, E. and Delgado, I. M. (2007) *European Administrative Law in the Constitutional Treaty* (Oxford and Portland, Oregon: Hart Publishing), at p. 159; Alemanno 2007, loc. cit. n. 106, at p. 15.

¹¹⁵ Bovens 2007, loc. cit. n. 85, at p. 112.

¹¹⁶ Vos 2000, loc. cit. n. 8, at p. 1125.

¹¹⁷ Ibid.

¹¹⁸ Ibid.

¹¹⁹ Regulation (EC) No. 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents *OJ* [2001] L 145/43, cf. Preamble, Recital 8; Article 9(1).

referred to as ‘fire-alarm monitoring’), with the principals relying on third parties for the detection of malfunctions within the agency.¹²¹ Connected to this form of oversight is the agencies’ role in networking as the majority of agencies is embedded in, or even acts as the European focal point of, a variety of networks consisting of national authorities or institutions. Again, those networks fulfil a supervisory function.

Administrative Accountability

Finally, administrative accountability relates to the creation of systems of checks and balances within the administration, including, for example, the establishment of an Ombudsman (who is able to investigate cases of maladministration), internal auditors or independent inspectors.¹²²

II.5 Conclusion

The main aim of this first Chapter was to convey a general overview of what a European Agency is and which problems have been encountered in the exercise of delegating powers. To illustrate the delegation process, the principal-agent framework was found to be best suited. Even though this framework can also be applied to the European level, to do so has proven to be much more difficult than at national level. Reasons therefore mainly include the EU’s multi-level structure of governance (encompassing the national, subnational and supranational level), which was found to lead to the emergence of multiple principals as well as a web of accountability relations, making it considerably more difficult for the principal(s) to control its/their agents at European level than at national level.

Those problems inherent in the delegation of powers at European level have been dealt with by the Court of Justice already in the *Meroni* judgments of 1958. The judgments resulted in the anti-delegation doctrine which is, despite major criticism, still valid today. In order to comply with the doctrine’s conditions, only few agencies have so far been delegated the power to adopt independent decisions; in the exceptional cases in which those powers were delegated, stringent criteria have been followed. The last Section was devoted to providing an overview of the most important existent forms of how to hold agencies accountable and to ensure their control.

¹²⁰ Vos 2000, loc. cit. n. 8, at p. 1126.

¹²¹ Keleman 2002, loc. cit. n. 20, at p. 97.

¹²² Bovens 2007, loc. cit. n. 85, at p. 110.

III – The European Chemicals Policy

Having gained a general background on the emergence of European agencies and the complex of problems connected to the delegation of powers, this Chapter will provide for an overview of the European Chemicals Policy, before and after its major review in 1998.

Overall, the European Union's chemical industry is the world's largest chemical production, with about 4.7 million jobs being (in)directly dependent on it.¹²³ Yet, next to the industry's economic importance, chemicals are capable of causing enormous harm to human health and the environment and have been responsible for the suffering and premature death of thousands of people worldwide.¹²⁴ Therefore, any European chemicals policy is naturally confronted with a dual challenge: whereas it is of utmost importance to ensure a sufficiently high level of protection of human health and the environment on the one hand, the smooth functioning of the internal market and, therewith, the preservation of the competitiveness of the European chemicals industry have to be guaranteed on the other.¹²⁵

III.1 The Failure of the Old EU Chemicals Policy

In 1998, the European Environment Ministers acknowledged the need for an overall review of the present EU chemicals policy – with alarming results.¹²⁶ The most precarious gap revealed was the distinction between old ('existing') chemicals and new (introduced on the European market after 1981) chemicals, on which the old chemicals policy was based.¹²⁷ Whereas all 'new' substances entering the EU market were subject to a notification and risk assessment requirement, such requirements were simply lacking for existing substances, which amounted to around 99 percent of the total volume of substances on the EU market in 2001.¹²⁸ The result was a huge gap in knowledge about existing substances, with adverse consequences not only for human health and the environment, but also for innovation by discouraging the search for new, less harmful substances.¹²⁹ In the beginning of the 1990s, the Council undertook a first attempt to reform the system by adopting Regulation (EEC)

¹²³ European Commission, *Strategy for a Future European Chemicals Policy*, White Paper, COM(2001) 88 final, 27 February 2001, Brussels, p. 4.

¹²⁴ Ibid.

¹²⁵ Ibid., p. 5.

¹²⁶ Ibid., p. 6.

¹²⁷ Heyvaert, V. (2008) 'The EU Chemicals Policy: Towards Inclusive Governance?', in: E. Vos (ed.) *European Risk Governance - Its Science, its Inclusiveness and its Effectiveness*, Connex Report Series No. 6 (Mannheim: University of Mannheim), at p. 4.

¹²⁸ European Commission, *Strategy for a Future European Chemicals Policy*, see *supra* n. 123, at p. 6.

¹²⁹ Heyvaert 2008, loc. cit. n. 123, at p. 5.

793/93 on existing substances,¹³⁰ which obliged manufacturers and importers to report all available information about existing chemicals to the European Chemicals Bureau (ECB).¹³¹ The ECB, today referred to as the Consumer Product Safety and Quality (CPS&Q) Unit, operates as a scientific committee within the Joint Research Centre, and was (and still is) directly dependent on the European Commission.¹³² According to priority lists, substances were assigned to different national authorities for further assessment.

Yet, the whole system proved to be a failure. Most problematic, the system lacked any incentives for producers and importers to report information to the Commission; on the one hand, penalties in case of failure to report hardly served as a deterrent.¹³³ Compliance, on the contrary, implied the risk of the (potentially) dangerous chemical being restricted or completely prohibited, hence including high losses for the respective industry.¹³⁴ Moreover, the responsibility for risk assessments rested primarily on national regulatory authorities (NRAs) instead of on the industry; this meant that the NRAs first had to request all relevant information from the industry, which resulted in significant delays and immense costs.¹³⁵

Eventually, after extensive consultation with stakeholders, the Commission published its White Paper ‘Strategy for a Future Chemicals Policy’ in 2001.¹³⁶ Herein, it proposed a fundamental reform of the EU chemicals policy, advocating the implementation of a completely new system called REACH – Registration, Evaluation and Authorisation of Chemicals.¹³⁷ In 2003, the Commission presented its Proposal on REACH to the Council;¹³⁸ yet, it took three more years of consultations and complex bargaining before Regulation 2006/1907/EC concerning the registration, evaluation, authorisation and restriction of chemicals (hereafter ‘REACH Regulation’), consisting of 849(!) pages, finally entered into force on 1 June 2007.

¹³⁰ Council Regulation (EEC) No. 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances *OJ* [1993] L 84.

¹³¹ See *supra* n. 123, p. 6.

¹³² European Commission (2008) *Consumer Products Safety & Quality (CPS&Q) Unit*, available at: <<http://ecb.jrc.it/>>.

¹³³ Heyvaert 2008, loc. cit. n. 127, at p. 5.

¹³⁴ Calliess C. and Lais, M. (2005) ‘REACH revisited – Der Verordnungsvorschlag zur Reform des Chemikalienrechts als Beispiel einer neuen europäischen Vorsorgestrategie’, *Natur und Recht* 5, at p. 291.

¹³⁵ See *supra* n. 123, at p. 6.

¹³⁶ See *supra* n. 123. For a review of and comments on the White Paper, see Rogers, M. D. (2003) ‘The European Commission’s White Paper “Strategy for a Future Chemicals Policy”: A Review’, *Risk Analysis* 23(2).

¹³⁷ *Ibid.*, at p. 16.

¹³⁸ Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}, COM/2003/0644 final.

III.2 REACH – “No Data, No Market”

Contrary to the previous chemicals policy, REACH establishes a uniform system applicable to all chemicals (i.e. including existing and new ones) that exceed a certain annual production/importation threshold.¹³⁹ The system consists of three distinct phases: registration, evaluation and authorisation. However, not every chemical has to pass through each stage; whether a chemical must do so depends on its scheduled production volume, its proved/estimated dangerousness, its purpose of use and the degree of exposure to humans and the environment.¹⁴⁰ A further central feature of REACH lies in the fact that the primary responsibility for the safety and assessment of chemicals was shifted away from the NRAs to the industry itself.¹⁴¹ To gain a better understanding of REACH, the three stages will be briefly outlined.

Registration: Title II of the REACH Regulation deals with the registration of substances; based on the slogan “no data, no market”, it is stipulated that no substance exceeding an annual production volume of one tonne can be marketed in the EU without prior registration.¹⁴² To register, the industry is required to hand in a “technical dossier”, entailing health, safety and environmental data about the substance; in case of production volumes exceeding ten tonnes per year, an additional and more detailed “chemicals safety report” must be submitted.¹⁴³

Evaluation: The evaluation procedure is determined in Title VI of the REACH Regulation. According to Article 40, every technical dossier submitted pursuant to the registration requirement must be checked for completeness; in addition, five percent of the registrations are subject to a more extensive compliance check.¹⁴⁴ Furthermore, a substance evaluation must be carried out where the initial data provided in the dossier give rise to concerns about the substance’s health or environmental effects.¹⁴⁵ “EC rolling action plans” are created according to which these potentially dangerous substances are assigned to the different national regulatory authorities for thorough evaluation.¹⁴⁶

Authorisation: In case suspicions were confirmed within the scope of the substance evaluation procedure (cf. above), Title VII imposes an authorisation requirement for

¹³⁹ Rogers 2003, loc. cit. n. 136, at p. 384.

¹⁴⁰ Calliess and Lais 2005, loc. cit. n. 134, at p. 293.

¹⁴¹ REACH Regulation, Article 1(3).

¹⁴² REACH Regulation, Article 6(1). See also Heyvaerts 2008, loc. cit. n. 127, at p. 9.

¹⁴³ REACH Regulation, Articles 10 and 14. See also Heyvaerts 2008, loc. cit. n. 127, at p. 9; Hanson B. G. and Blainey M. (2006) ‘REACH: A Step Change in the Management of Chemicals’, *RECIEL* 15(3), at p. 271 and 275.

¹⁴⁴ REACH Regulation, Article 41. See also Hanson and Blainey 2006, loc. cit. n. 143, at p. 276.

¹⁴⁵ Heyvaerts 2008, loc. cit. n. 127, at p. 10.

¹⁴⁶ REACH Regulation, Article 44. See also Heyvaerts 2008, loc. cit. n. 127, at p. 10.

“substances of very high concern”.¹⁴⁷ Substances listed in Annex XIV of the REACH Regulation may not be marketed in the EU unless previously approved.¹⁴⁸ Furthermore, it is the applicant (i.e. the industry), not the national authority, the Commission or the ECHA, who has to provide proof (in terms of a risk assessment and management report) that the risks inherent in the chemical are adequately contained.¹⁴⁹ Granted authorisations are to be reviewed regularly.¹⁵⁰ As an alternative to authorisation, EC-wide restrictions on the production, marketing and/or use of the dangerous substance at issue may be imposed.¹⁵¹

III.3 Conclusion

A European chemicals policy has been found to be naturally confronted with the dual challenge of reconciling the protection of public health and the environment with concerns about the competitiveness of the European chemicals industry and a smooth functioning of the internal market. Apparently, the ‘old’ EU chemicals policy was unable to meet these demands. The result was a significant data gap on so-called existing substances jeopardising public health and environmental protection alike. The new chemicals policy, which is coined by the REACH system, is expected to remedy these shortcomings by offering a uniform, centralised system, operating under the slogan of “no data, no market”. Having sketched the main characteristics of the REACH system, it is now time to turn to the Chemicals Agency and to analyse its role therein.

IV – The European Chemicals Agency

To achieve the desired reform of the EU chemicals policy, a central entity, co-ordinating and administering the system at European level, was required.¹⁵² Under the ‘old’ policy, it was the national authorities which functioned as the main reference point for the European chemicals industry; applications and requests were to be addressed to them.¹⁵³ The European Chemicals Bureau, as part of the European Commission’s Joint Research Centre,

¹⁴⁷ REACH Regulation, Article 55. See also Heyvaerts 2008, loc. cit. n. 127, at p. 11; Hanson and Blainey 2006, loc. cit. n. 143, at p. 272.

¹⁴⁸ REACH Regulation, Article 56.

¹⁴⁹ Ibid., Article 63. See also Heyvaerts 2008, loc. cit. n. 127, at p. 11.

¹⁵⁰ Ibid., Article 61.

¹⁵¹ Ibid., Title VIII. See also Hanson and Blainey 2006, loc. cit. n. 143, at p. 272.

¹⁵² European Commission, *Strategy for a Future European Chemicals Policy*, see supra n. 123, at p. 25.

¹⁵³ Heyvaerts 2008, loc. cit. n. 127, at p. 13.

provided for the scientific and technical support.¹⁵⁴ The result was an opaque division of competences between national authorities, Commission and the ECB, which hampered a proper functioning of the Internal Market in that sector.¹⁵⁵ The then ECB was found to be inadequate to perform the function of the central entity, on the one hand, due to its dependence on the European Commission and, on the other, because of the insufficiency of its resources and capacities.

The creation of an independent Agency to act as the central entity was found to be the best solution: recalling the debate in Chapter II, Agencies have been regarded as *the* solution to the Commission's 'regulatory problem' and have been hoped to facilitate the employment of scientific experts, reduce the Commission's workload and screen scientific assessment from political pressures.¹⁵⁶ After a long process of consultation and negotiations, the new European Chemicals Agency was eventually created by Article 75 of the REACH Regulation as an integral part of the new chemicals policy. As most of the recently created agencies, ECHA is no longer based on Article 308 EC but on Article 95 EC on the establishment and functioning of the internal market. Its location is in Helsinki, Finland.

The research focus of this Thesis is devoted to the nature of the Chemicals Agency's decision-making powers, and more precisely to these powers' compatibility with the long-standing *Meroni* conditions of 1958. However, in order to analyse the Agency's decision-making powers, it is necessary to first understand its organisational structure and main tasks within the REACH system. Doing so, the starting point of this analysis will be the structure, tasks and decision-making procedures of already existing agencies whose compatibility with the *Meroni* doctrine has long been accepted; hereby, EMEA and EFSA, as regulatory agencies without decision-making powers, and the existing regulatory agencies with decision-making powers, will serve as the basis of comparison. That way, particularities in the Chemicals Agency's design and decision-making powers may be better discerned and analysed.

IV.1 Organisational Structure

According to the aforementioned comparative method, this Section will, before analysing the organisational structure of ECHA, start with an introduction to the 'classical' design of a regulatory agency without decision-making powers and to that of the existing agencies with

¹⁵⁴ ECB (2008) *Activities*, available at: <<http://ecb.jrc.it/activities/>>.

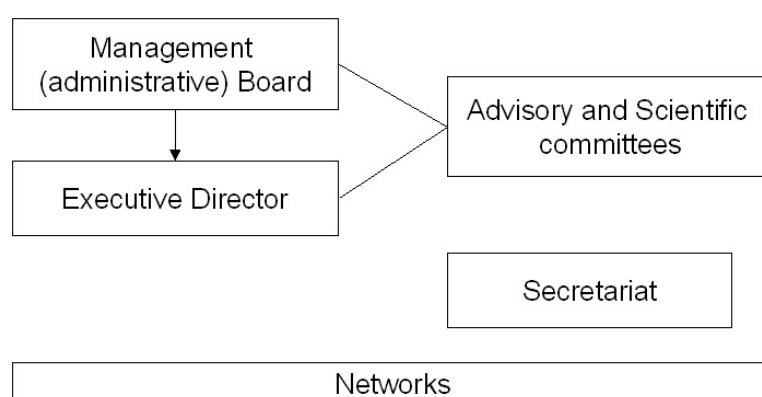
¹⁵⁵ European Commission, *Strategy for a Future European Chemicals Policy*, see supra n. 123, at pp. 10 and 11.

decision-making powers. Subsequently, particularities in the Chemicals Agency’s design can be distinguished.

IV.1.1 The ‘Classical’ Structure of a Regulatory Agency

The ‘classical’ regulatory agency¹⁵⁷ consists of a Management Board (in some agencies also referred to as the Administrative Board), an Executive Director, depending on the tasks of the agency either scientific or technical committees or both, disposes of an own secretariat, and is the focal point of diverse networks (see Figure 2).¹⁵⁸

Figure 2: ‘Classical’ Structure of Regulatory Agencies



Generally, the Management (or Administrative) Boards are composed of Member State representatives as well as one or several Commission representatives. The Boards of the more recently created agencies also include representatives from the EP, reflecting the Parliament’s increase in legislative power within the scope of the co-decision procedure.¹⁵⁹ Overall, Management Boards act as the agencies’ central authority; they establish general guidelines and work programmes.¹⁶⁰ Through them, Commission and Member States are able to control and exert influence over the agencies’ activities.¹⁶¹ The Executive Director is normally appointed by the Management Board and is responsible for the agency’s day-to-day management. Furthermore, he acts as the legal representative of the agency.¹⁶² Advisory or scientific committees are composed of experts, either advising the Management Board

¹⁵⁶ Vos 2000, loc. cit. n. 8, at p. 1119.

¹⁵⁷ Cf. Figure 1.

¹⁵⁸ Vos 2003, loc. cit. n. 3, at p. 122.

¹⁵⁹ cf. European Commission (2008) *Functions of Community Agencies*, available at: <http://europa.eu/agencies/community_agencies/function/index_en.htm>.

¹⁶⁰ Ibid.

¹⁶¹ Vos 2003, loc. cit. n. 3, at p.122.

¹⁶² See *supra* n. 159.

(e.g. budgetary committees) or the Executive Director on scientific or highly technical questions for the preparation of opinions.¹⁶³

The European Medicines Agency's structure is very close to that of a 'typical' regulatory agency: it consists of a Management Board composed of one representative from each Member State, two representatives of the Commission and EP respectively and four representatives of stakeholder organisations.¹⁶⁴ Moreover, EMEA is managed by an Executive Director and is advised by five specialised scientific committees consisting of national experts.¹⁶⁵

By contrast, the organisational structure of EFSA differs in some respects from the 'classical' agency design; instead of being composed of national representatives, EFSA's Management Board is made up of 14 members appointed by the Council, based on a list compiled by the Commission.¹⁶⁶ Yet, in order to compensate for the resulting loss of Member State control over the Agency's functioning, a further organ was created within EFSA: the Advisory Forum.¹⁶⁷ The Advisory Forum consists of national representatives and advises the Executive Director on the agency's work programmes and priorities; furthermore, its task is to ensure the smooth functioning of the network, i.e. the collaboration and consultation with national food authorities.¹⁶⁸ Related to this network function, the Advisory Forum shall guarantee a close co-operation between the Agency and the national competent authorities where a "substantive divergence over scientific issues has been identified".¹⁶⁹ Eventually, the Advisory Forum's mandate includes a conciliation function in case of disagreement over scientific findings.

IV.1.2 The Structure of Existing Regulatory Agencies with Decision-Making Powers

The organisational structure of those regulatory agencies which have been granted independent decision-making power varies from the design of the 'classical' regulatory agency. Taking OHIM's structure, this agency too disposes of an Administrative Board, also consisting of one representative per Member State plus one representative of the Commission.¹⁷⁰ Yet, the Board's role is considerably limited in comparison to that of the

¹⁶³ Ibid.

¹⁶⁴ EMEA Regulation, Article 65(1).

¹⁶⁵ Ibid., Article 56(1).

¹⁶⁶ General Food Law, Article 25(1).

¹⁶⁷ Ibid., Article 27.

¹⁶⁸ Ibid.

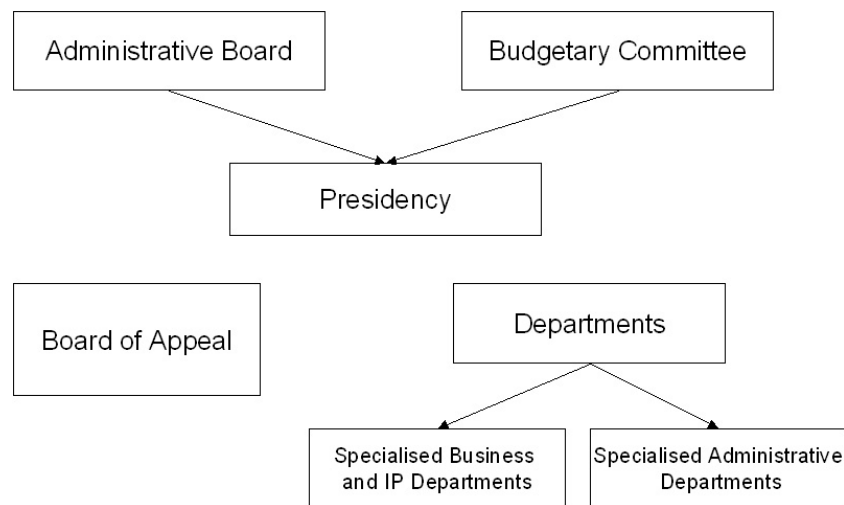
¹⁶⁹ Ibid., Articles 27(4)(b) and Article 30(4).

¹⁷⁰ Trade Mark Regulation, Article 122.

typical regulatory agency.¹⁷¹ Instead of the Administrative Board, it is OHIM’s President who acts as the central authority and who oversees and manages the Agency;¹⁷² the Administrative Board merely “advises” the President, must be “consulted”, and “may deliver opinions and requests for information to the President and to the Commission”.¹⁷³ OHIM’s President is, unlike an Executive Director, not appointed by the Administrative Board but is directly elected by the Council.¹⁷⁴ In place of committees, the Trade Mark Office disposes of different specialised departments which are broadly divided into administrative and technical (business) support.

The most distinctive feature of the Trade Mark Office is the Board of Appeal which is granted authority to decide on appeals from decisions taken by the Office.¹⁷⁵ Whereas the President of the Board of Appeal is, similar to the President of the Office, elected by the Council, the Board’s members are appointed by the Administrative Board.¹⁷⁶ The design of CPVO is virtually identical to that of OHIM.

Figure 3: Structure of OHIM (CPVO)



The structure of the third and most recently created existent Community Agency with decision-making powers, EASA, resembles at first sight rather that of the classical regulatory agency than that of OHIM. Similar to the classical regulatory agency, EASA consists of a Management Board, composed of Member State and one Commission

¹⁷¹ Hofmann H. and Türk A. (2006) ‘Policy Implementation’, in: H. Hofmann and A. Türk (eds.), *EU Administrative Governance* (Cheltenham: Edward Elgar Publishing), at p. 87.

¹⁷² Trade Mark Regulation, Article 119.

¹⁷³ *Ibid.*, Article 121(4-6).

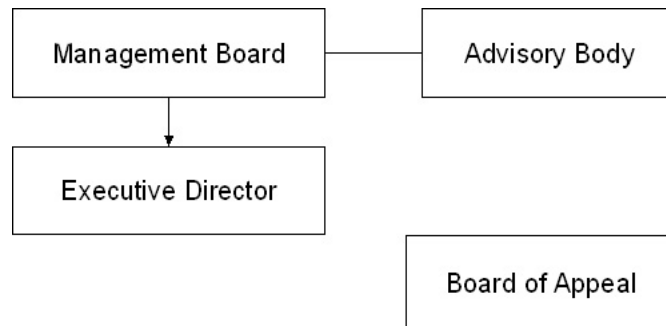
¹⁷⁴ *Ibid.*, Article 120.

¹⁷⁵ *Ibid.*, Article 130.

¹⁷⁶ *Ibid.*, Article 131.

representative,¹⁷⁷ and an Executive Director, who is appointed by the Management Board.¹⁷⁸ Different to OHIM, it is EASA’s Management Board which acts as the central authority of the Agency and exerts disciplinary authority over the Executive Director;¹⁷⁹ Yet, similar to OHIM, also EASA disposes of a Board of Appeal.¹⁸⁰ Interesting is the existence of an Advisory Body within EASA’s structure, which is established by the Management Board and shall be composed of interested parties and stakeholder organisations.¹⁸¹ Before taking a decision, the Management Board must consult the Advisory Body, however, the “Management Board shall not be bound by the opinion of the advisory body”.¹⁸² Four members of the Advisory Body may participate as observers in meetings of the Management Board.¹⁸³

Figure 4: Structure of EASA



Having looked at the structure of existing regulatory agencies, with and without decision-making powers, the discussion will now turn to ECHA. What, if any, particularities can be discerned in the Chemicals Agency’s structure?

IV.1.3 The Structure of ECHA

According to Article 76 of the REACH Regulation, ECHA is composed of a Management Board, an Executive Director, two scientific/technical committees (the Committee for Risk

¹⁷⁷ EASA Regulation, Article 34(1).

¹⁷⁸ Ibid., Article 39(1).

¹⁷⁹ Ibid., Article 33(2).

¹⁸⁰ Ibid., Article 40(1).

¹⁸¹ Ibid., Article 33(4). More precisely, the Advisory Body consists of Aviation Personnel (five members), one members from Aviation Sports, General/Non-Commercial Aviation Operators (three members), one member from the Maintenance Industry, Manufacturers (five members), six Commercial Operators, and one member from the Training Industry. A list of Members is available at:

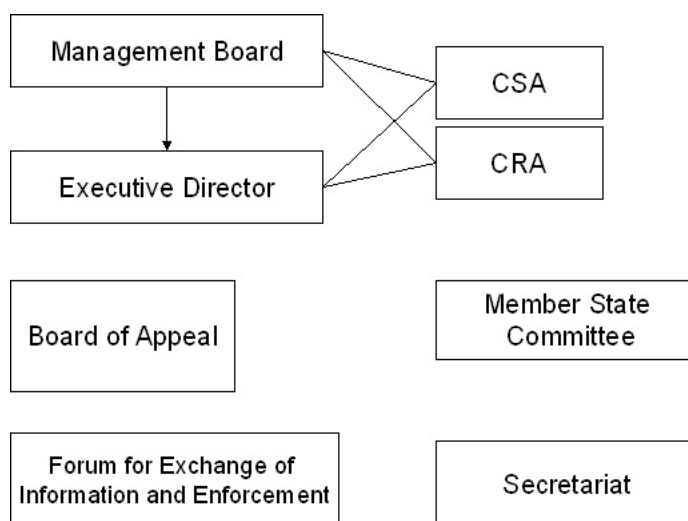
<http://www.easa.europa.eu/ws_prod/g/doc/mngboard/List%20of%20EAB%20Members%2011%20May%202007.pdf>.

¹⁸² EASA Regulation, Article 33(4).

¹⁸³ Ibid., Article 34(3).

Assessment (CRA) and the Committee for Socio-economic Analysis (CSA)), a Member State Committee, a Forum for the Exchange of Information on Enforcement (the Forum), a Secretariat and a Board of Appeal (see Figure 5 below).

Figure 5: Structure of the ECHA



The *Management Board* of ECHA is composed of one representative per Member State, six representatives appointed by the Commission, three individuals from interested parties and two independent persons appointed by the EP.¹⁸⁴ The Management Board adopts the Agency’s annual and multi-annual work programmes, and appoints the Agency’s staff – reaching from the members of the scientific/technical committees and the Board of Appeal to the Executive Director.¹⁸⁵ The *Executive Director* is, next to being ECHA’s legal representative, responsible for the day-to-day management and the internal co-ordination between the committees and the Forum. The Director, moreover, prepares the draft opinions to be adopted by the Management Board as well as the Agency’s budget.¹⁸⁶ The two scientific/technical committees, *CSA and CRA*, are composed of experts nominated by the Member States, which are formally approved by the Management Board.¹⁸⁷ Their task is to draw up opinions at the request of the Executive Director and to provide scientific or technical advice to the Management Board, the Director, and to the NRAs.¹⁸⁸

Article 76 of the REACH Regulation, furthermore, establishes the *Member State Committee*. It consists of national representatives, which are, different to the members of

¹⁸⁴ REACH Regulation, Article 79.

¹⁸⁵ Ibid., Article 78.

¹⁸⁶ Ibid., Article 83.

¹⁸⁷ Ibid., Article 85.

¹⁸⁸ Ibid., Article 77(3).

the CSA and the CRA, directly appointed by their respective Member States; no approval of the Management Board is required.¹⁸⁹ According to Article 76, the Committee is responsible for the resolution of “potential divergences of opinions on draft decisions proposed by the Agency or the Member States”. Beyond doubt, the existence of such a Committee is highly unusual and does not appear in any of the other agencies analysed; yet, when having a closer look at its mandate, one can find similarities to that of EFSA’s Advisory Forum: as it has been described above, the Advisory Forum’s tasks include, *inter alia*, the guarantee of co-operation between EFSA and the national food authorities in case of diverging scientific opinions. Closer attention will therefore be paid to the Member State Committee in the following sections.

The Chemicals Agency further consists of a Forum for the Exchange of Information and Enforcement and of a Board of Appeal. The *Forum*’s members are appointed by the Member States (one per Member State).¹⁹⁰ And, as the name suggests, its main role is the co-ordination and harmonisation of national policies and regulatory authorities with respect to the enforcement of an EU chemicals policy.¹⁹¹ Finally, the *Board of Appeal*¹⁹² consists of a Chairman and two further members, appointed by the Management Board on the basis of a list of candidates drawn up by the Commission.¹⁹³ Appeals may be brought against decisions taken by the Agency.¹⁹⁴

IV.1.4 Particularities in ECHA’s Structure

Evidently, ECHA’s structure seems to resemble that of the ‘classical’ regulatory agency and is thus more similar to EASA’s design than to that of OHIM (resp. CPVO). The Chemicals Agency consists, like the classical regulatory agency, of a Management Board, an Executive Director, and scientific committees. The composition of EFSA’s Management Board was, obviously, unable to establish itself, even though a similar composition was originally considered in the Commission’s REACH proposal: according to the proposal, the Management Board should have consisted of six representatives nominated by the Council, six Commission representatives and three individuals from interested parties.¹⁹⁵ During the co-decision procedure, however, not only the Member States in the Council, but also the EP could assert their influence.

¹⁸⁹ *Ibid.*, Article 85(3).

¹⁹⁰ *Ibid.*, Article 86(1).

¹⁹¹ *Ibid.*, Article 77(4).

¹⁹² *Ibid.*, Article 89.

¹⁹³ *Ibid.*, paragraph 2 and 3.

¹⁹⁴ *Ibid.*, Article 91.

¹⁹⁵ Commission Proposal, see *supra* n. 138, Article 79.

Yet, similar to EFSA, also ECHA comprises a Forum, composed of Member State representatives, with the task of consulting/collaborating with the national regulatory authorities in order to ensure a higher degree of harmonisation in the enforcement of an EU chemicals policy. Strikingly, EFSA's Advisory Committee serves a further purpose, which resembles that of the novel Member State Committee in ECHA's structure, namely the reconciliation of diverging opinions. Hence, it appears that the function of EFSA's Advisory Forum has been split within ECHA's structure into that of the Forum (responsible for the harmonisation of national enforcement policies) and into that of the Member State Committee (responsible for the resolution of controversial opinions). The question that now arises is whether these two organs within ECHA are only formally two distinct bodies, with the Member State Committee being the *alter ego* of the Forum, or vice versa.

Indeed, Article 86, which determines the composition of the Committees and the Forum, does not prohibit a person to be a member to both organs. Comparing the list of members of the two organs,¹⁹⁶ one finds that the representatives of two countries, of Greece and of Cyprus, are at the same time members of both organs. At this point it is of course tempting to assert that there is only an artificial, 'formal' distinction between Forum and Member State Committee. Yet, as 25 out of 27 Member States appointed different persons to these two organs, such an assertion appears overhasty. The reason behind this separation of functions within ECHA's structure will hopefully be illuminated in the subsequent sections of this Chapter.

Important to notice is furthermore that an Advisory Body composed of stakeholder organisations, like that existent in EASA's design, does not appear in ECHA's structure. Stakeholders or interested parties are permanently represented only as observers in ECHA's Management Board. Finally, the only component taken over from OHIM's structure is the Board of Appeal: ECHA disposes, like all other agencies with decision-making power, of an internal Board of Appeal.

IV.2 Tasks

Similar to the previous Section on the Agency's structure, also this Section will examine the Chemicals Agency's tasks on basis of a comparison with existing agencies. EMEA and EFSA on the one hand, and OHIM on the other, will prove to be best suited for this

¹⁹⁶ The list of members of the Member State Committee is available at: <http://echa.europa.eu/about/organisation/committees/ms_members_en.asp>; the list of members of the Forum is available at: <<http://echa.europa.eu/doc/about/organisation/20080225MembersOfForum.pdf>>.

comparison. Overall, the Chemicals Agency can be said to be responsible for the management of the REACH system, within which it fulfils two core functions: firstly, it provides scientific and technical expertise on chemicals to Member States and EU institutions; secondly, it acts as the chief administrator of the centralised REACH system at European level.¹⁹⁷

Both, EFSA and EMEA, are primarily involved in the risk regulation process, of food and of medicines respectively. This process consists of three main elements: firstly, the risk assessment encompassing the risk's scientific evaluation; secondly, the risk management referring to the adoption of policy decisions on how a risk shall be treated; and thirdly, the risk communication through which the general public and stakeholders are informed about the risk.¹⁹⁸ Generally, the Commission's policy towards risk regulation after the food crises of the 1990s¹⁹⁹ aimed at a functional separation between the risk assessment stage and the risk management stage;²⁰⁰ by every means was a political pressure on the scientific risk assessment to be avoided. In order to guarantee such a functional separation between risk assessment and risk management, the risk regulation process of medicinal products and food in the European Union was decided to be insulated also from an institutional perspective, with the risk assessment being carried out by the 'independent' agencies (EMEA and EFSA) and the risk management being performed by the Commission.²⁰¹

Accordingly, their constituent regulations assigned EFSA and EMEA, for food and medicinal products respectively, an important role at the risk assessment and risk communication stage. Thus, within the scope of the risk assessment, the Agencies are responsible for the drawing up of scientific opinions, which are submitted to the Commission for eventual adoption.²⁰² EMEA is, furthermore, the receiving body for all applications made for the authorisation of medicinal products under the central authorisation procedure.²⁰³ Both agencies are engaged in risk communication, by informing the public

¹⁹⁷ cf. Heyvaert 2008, loc. cit. n. 127, at p. 13.

¹⁹⁸ Vos, E. and Wendler, F. (2006) 'Food Safety Regulation in Europe: A comparative institutional analysis', in: Vos, E. and F. Wendler (eds.), *Food Safety Regulation in Europe: A Comparative Institutional Analysis* (Antwerp: Intersentia), at p. 66.

¹⁹⁹ Especially after the BSE crisis.

²⁰⁰ James, P., Kemper F. and Pascal, G. (1999) *A European Food and Public Health Authority. The future of scientific advice in the EU* (Brussels: European Commission DG Sanco), available at: <http://ec.europa.eu/food/fs/sc/future_food_en.pdf>.

²⁰¹ Ibid.

²⁰² General Food Law, Article 23; EMEA Regulation, Article 5.

²⁰³ EMEA Regulation, Article 5(2). The authorisation of medicinal products may be conducted according to two distinct procedures: a centralised procedure and a decentralised one. Whereas "less innovative products" may be authorised under the decentralised authorisation procedure, high-technology medicinal products have to be authorised under the centralised authorisation procedure. Under the centralised authorisation procedure,

and publishing relevant information on their websites.²⁰⁴ A further part of their tasks consists of networking with relevant national authorities and institutions.²⁰⁵ Following the Commission's strict functional separation between risk assessment and risk management, the two agencies are formally not involved in the risk management process. However, experience has shown that such a strict separation is unfeasible in practice as a close co-operation between risk assessor and risk manager is inevitable for an efficient risk regulation.²⁰⁶ Thus, in practice, there is much more interaction, in form of information exchange and co-ordination, between risk assessors and risk managers than the institutional separation would predict.²⁰⁷

The Trade Mark of Office and the European Aviation Safety Agency are not engaged in a risk regulation process. OHIM is the Community's central office for the registration of the Community Trade Mark (CTM) and the Registered Community Design (RCD), which are, once registered, valid throughout the European Union.²⁰⁸ EASA is engaged in three main fields of activity: firstly, it provides scientific advice and assistance to the EU institutions; secondly, it is allowed to issue continued airworthiness and environmental certificates for aircraft and its components. Finally, it is responsible for the conduct of standardisation inspections of the national aviation authorities of the Member States.²⁰⁹

Turning to ECHA, the European Chemicals Agency is, as the policy's 'central entity', involved in all three stages of the REACH system – i.e. in the registration, evaluation and authorisation of chemicals. Similar to OHIM, the Chemicals Agency is responsible for the *registration* of all existing and new substances, which includes a completeness check of each registration as well as a compliance check of five percent of the registrations.²¹⁰ Yet, similar to EFSA and EMEA, the Chemicals Agency is also involved in the risk regulation process: within the *authorisation* procedure for “substances of very high

EMEA plays an essential role: it is the receiving authority for all authorisation applications made and, furthermore, drafts the scientific opinion on whether the authorisation should be granted or not. For further reading, see Gehring and Krapohl 2007, loc. cit. 80, at p. 214.

²⁰⁴ General Food Law, Article 23; EMEA Regulation, Article 57.

²⁰⁵ General Food Law, Article 23; EMEA Regulation, Article 55.

²⁰⁶ James *et al* 1999, op. cit. n. 200.

²⁰⁷ Vos and Wendler 2006, loc. cit. n. 198, at p. 119.

²⁰⁸ OHIM (2008) *About OHIM*, available at: <<http://oami.europa.eu/ows/rw/pages/OHIM/index.en.do>>.

²⁰⁹ EASA (2008) *European Aviation Safety Agency*, available at:

<http://www.easa.eu.int/ws_prod/g/g_whatwedo.php>. See also Vos 2003, loc. cit. n. 3, at p. 121.

²¹⁰ REACH Regulation, Article 7, 20 and 41. See also Hanson and Blainey 2006, loc. cit. n. 143, at p. 276; Calliess and Lais 2005, loc. cit. n. 134, at p. 294. Note that with respect to the compliance check, the Agency's tasks have been expanded considerably in comparison to those envisaged in the Commission proposal. Whereas, according to the proposal, the NRAs were responsible for the evaluation of the technical dossier, this task is, under the REACH Regulation, performed by the Agency.

concern”, ECHA acts, like EMEA, as the central receiving authority for all applications.²¹¹ Furthermore, ECHA’s scientific committees, the CRA and CSA, are involved in the risk assessment process through the preparation of opinions in which they advise the Commission on the risks inherent in substances and whether those should be authorised or not.²¹²

In addition to these functions, the Chemicals Agency also plays a role in the *evaluation* procedure of the REACH system. At this stage, the Agency is responsible for the drafting of the EC rolling action plan according to which substances are allocated to national competent authorities, which are responsible for their evaluation.²¹³ Furthermore, completed evaluations are sent back to the Agency. Thus, even though the agency is not involved in the evaluation itself, it co-ordinates the process.²¹⁴ Within the risk regulation process, the evaluation of a substance, i.e. the assessment of whether a chemical is to be classified as dangerous or not, must be classified as belonging to the risk management stage because different to a pure risk assessment, such an evaluation comprises the adoption of policy decisions.²¹⁵ Consequently, different to the clear institutional separation between risk assessment and risk management on which EFSA and EMEA are based, there appears to be no such separation in the new EU chemicals policy.

Eventually, the most obvious finding that can be deduced from the foregoing comparison is that the European Chemicals Agency is involved in an unusually high number of distinct tasks within the risk regulation process of chemicals. Apparently, ECHA is, like EFSA and EMEA, active in the risk communication as well as in the risk assessment process through the preparation of scientific opinions. Strikingly, the Agency also plays an important co-ordinating role in the risk management process, which constitutes a clear departure from the Commission’s strict policy of separation between risk assessment and management. On top, and very similar to OHIM’s function, ECHA carries out the central registration of all chemicals. Realising this impressive variety of tasks, it remains to be seen when and under which circumstances ECHA is able to exercise its decision-making power.

²¹¹ REACH Regulation, Article 62.

²¹² *Ibid.*, Article 60. Cf. Hanson and Blainey 2006, loc. cit. n. 143, at p. 276.

²¹³ *Ibid.*, Article 45.

²¹⁴ *Ibid.*

²¹⁵ See also Heyvaerts 2008, loc. cit. n. 127, at p. 10.

IV.3 Decision-Making Process

Having examined ECHA's organisational structure, on the one hand, and its tasks, on the other, it is possible to turn to the focal point of this Thesis and to look into the Agency's decision-making powers: when and under which circumstances is ECHA able to adopt independent decisions? Are its decision-making powers still compatible with the conditions established in the *Meroni* judgments? Answering these questions, this Section will one by one analyse the Chemicals Agency's decision-making powers within the different stages of the REACH system.

IV.3.1 Registration Phase

The previous Section has shown that both OHIM and ECHA perform similar functions when it comes to the registration of trade marks (and designs) and chemicals respectively. Regarding the fact that OHIM's decision-making powers have long been accepted as being in accordance with the *Meroni* doctrine, a comparison of the agencies' registration procedures may give interesting insights into the compatibility of ECHA's decision-making powers with the aforesaid doctrine.

For the registration of trade marks, on the one hand, and designs, on the other, OHIM follows very similar procedures; for illustration purposes, it therefore suffices to concentrate on one registration procedure, namely that for trade marks. As a first step, all applications for registration are submitted directly to OHIM. The Office then examines, first, whether the application complies with all the requirements and conditions established in the Trade Mark Regulation and its Implementing Regulation.²¹⁶ Second, it has to ensure that the registration fees have been paid.²¹⁷ In case the requirements and/or conditions are not fulfilled, the Office requests the applicant to remedy any deficiencies. If the deficiencies are not remedied within a given time-limit, the Office must reject the application and the registration process ends at this stage.²¹⁸ If the deficiencies are remedied, the application will be published on OHIM's website.²¹⁹ Within three month following publication, specified third parties (among others, proprietors of earlier trade marks) may file an opposition to the registration.²²⁰ After examination by the Office, this opposition may either be accepted (meaning the end of the registration process) or it may be refused. In case of

²¹⁶ Trade Mark Regulation, Article 36; Commission Regulation (EC) No 1041/2005 of 29 June 2005 amending Regulation (EC) No 2868/95 implementing Council Regulation (EC) No 40/94 on the Community trade mark (hereafter: 'Implementing Regulation') [2005] OJ L 172.

²¹⁷ Trade Mark Regulation, Article 36.

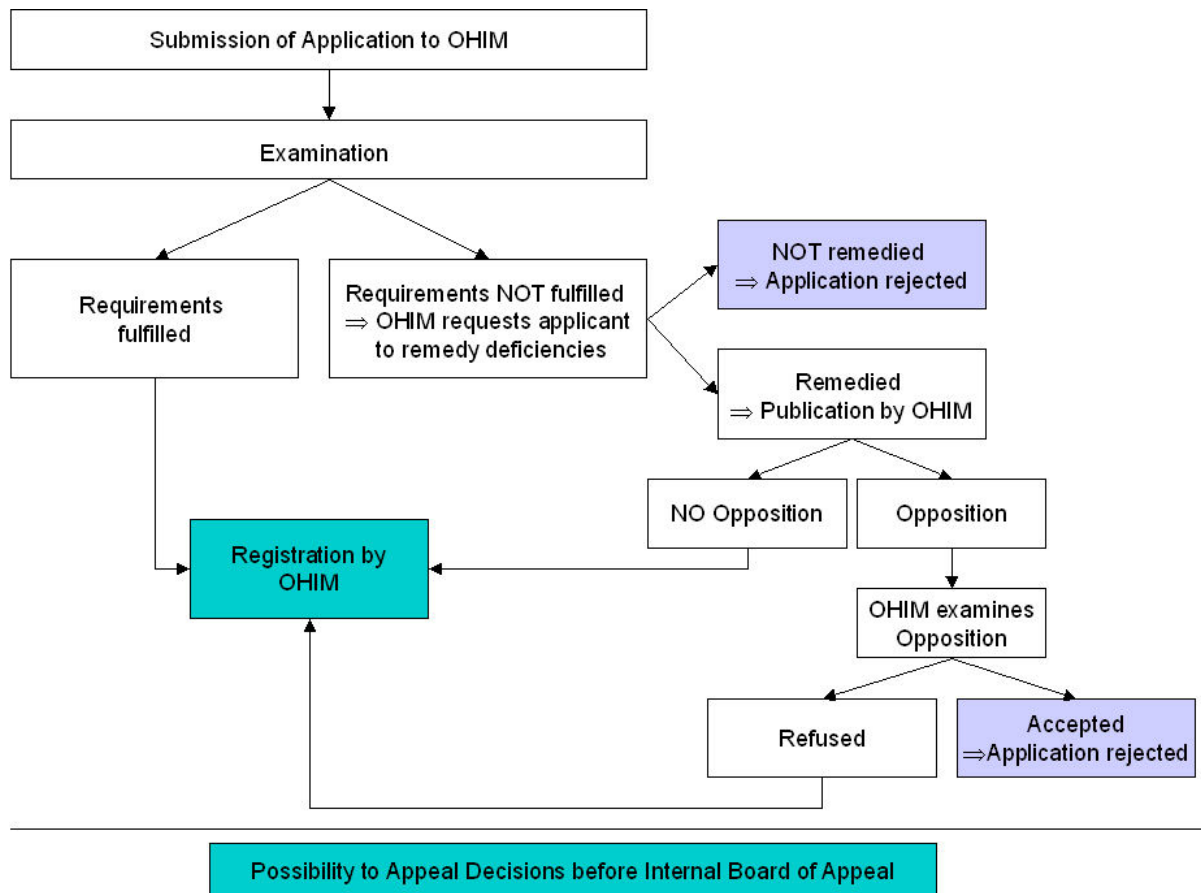
²¹⁸ Ibid.

²¹⁹ Ibid., Article 40.

²²⁰ Ibid., Article 43.

refusal, the trade mark will finally be registered.²²¹ All decisions taken by the Office may be challenged before the Board of Appeals.²²² The whole process is summarised in Figure 6.

Figure 6: OHIM's Registration Process



The foregoing shows that OHIM's registration process runs without any involvement of the Commission. Hence, the Office is able to adopt decisions in a completely independent way. Yet, it became also apparent that its decisions are based on previously and clearly defined criteria,²²³ denying the Office any opportunity to exercise discretion within the registration process. Thus, OHIM's powers are exclusively of an implementary nature.

Comparing OHIM's registration process to that of ECHA, it must first be noted that, as it has been alluded to above, ECHA's registration process comprises a completeness check of *each* registration²²⁴ and a so-called compliance check of *not less than five percent* of all registrations²²⁵ received by the Agency. Whereas the completeness check merely

²²¹ Ibid., Article 45.

²²² Ibid., Article 57.

²²³ The criteria are listed in Article 36 of the Trade Mark Regulation.

²²⁴ REACH Regulation, Article 20(4). See Calliess and Lais 2005, loc. cit. n. 134, at p. 295.

²²⁵ REACH Regulation, Article 41(5).

consists of a short examination of whether all elements required for registration have been handed in and whether the registration fees have been paid,²²⁶ the compliance check involves a more thorough investigation of whether the information submitted in the technical dossiers and chemical safety reports comply with the requirements set out in the REACH Regulation.²²⁷ The five percent of registrations to be evaluated are selected partly on the basis of certain specified criteria, partly on the basis of random selection.²²⁸ The fact that only spot tests of registrations are checked for compliance is mainly connected to a workload problem which the Agency encounters when being confronted with the registration of 30.000 existing substances.²²⁹ Thus, it can be argued that whereas OHIM follows one process for the registration of trade marks, the registration of chemicals may include two distinct processes.

Starting with the first process in ECHA's registration procedure, the completeness check, this process is very similar to that of the Trade Mark Office: the applications for registration are submitted to ECHA, which assigns each application a submission number.²³⁰ The Chemicals Agency then undertakes the completeness check in accordance with the criteria outlined in Article 20(2) of the REACH Regulation.²³¹ If the completeness check reveals that the registration is incomplete, the Agency requests the applicant to hand in the missing information. In case the applicant does not comply with the Agency's request, the application must be rejected.²³² In cases where the registration is complete, the substance is registered and ECHA notifies the competent authority in the Member State.²³³ Appeals may be brought before the internal Board of Appeal against decisions taken by the Agency.²³⁴ The procedure for the completeness check is depicted in Figure 7.

²²⁶ Ibid., Article 20(2). See also Hanson and Blainey 2006, loc. cit. n. 143, at p. 276.

²²⁷ REACH Regulation, Article 41(1).

²²⁸ Article 41(5) of the REACH Regulation stipulates that the 5 percent of the applications for registration shall be selected in the following way: "[t]he Agency shall give priority, but not exclusively, to dossiers meeting at least one of the following criteria." These criteria are listed in Article 41(5a-c).

²²⁹ Cf. Jacob, K. and Volkery, A. (2005) 'Europäische Rechtsetzung: Die Auseinandersetzungen zur Europäischen Chemikalienpolitik REACH und die Rolle nationaler Regierungen und Akteure im Policy-Prozess', *Technikfolgenabschätzung – Theorie und Praxis* 1, at p. 74.

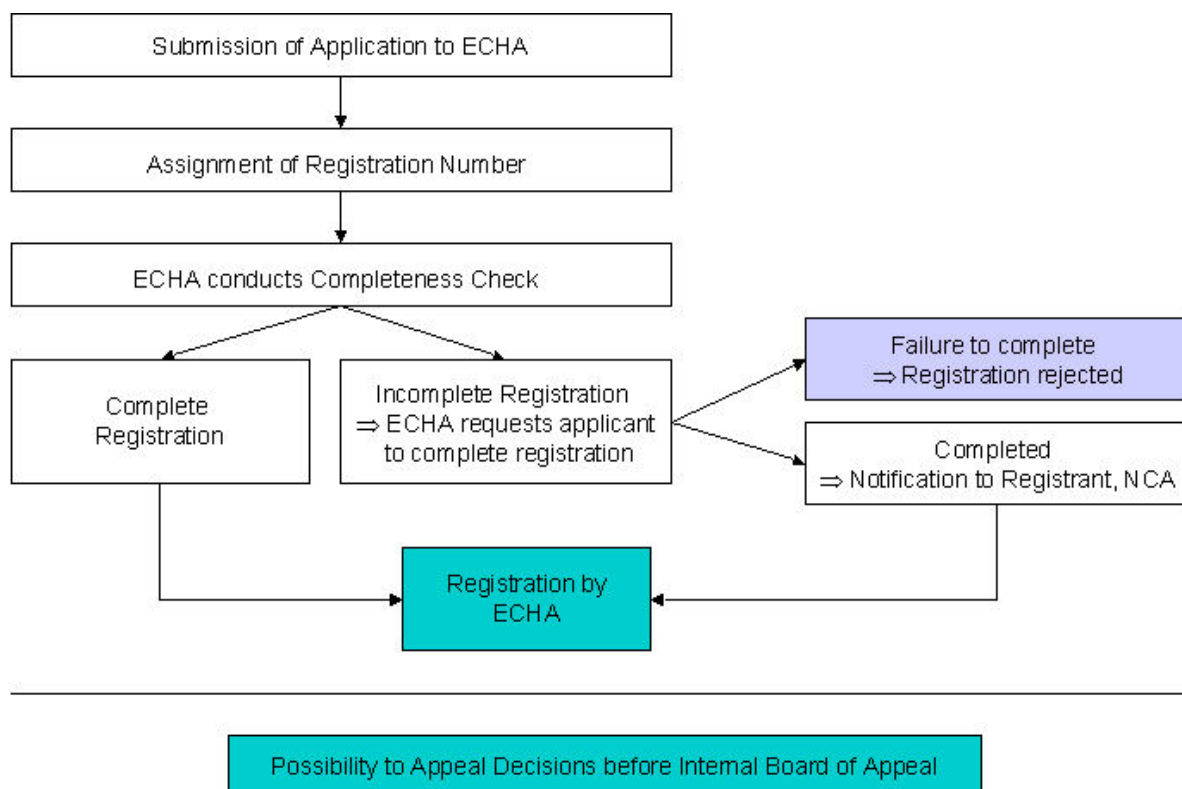
²³⁰ REACH Regulation, Article 20(1).

²³¹ Ibid., Article 20(2).

²³² Ibid.; Calliess and Lais 2005, loc. cit. n. 134, at p. 295.

²³³ REACH Regulation, Article 20(3) and 20(4).

Figure 7: Completeness check



Hence, similar to OHIM’s registration procedure, also the completeness check is conducted without any involvement of the Commission but is based on clearly defined criteria, allowing no room for discretionary decisions on part of ECHA.

Yet, five percent of the registrations are, in addition to the completeness check, also subject to the more extensive compliance check.²³⁵ The procedure followed hereunder is quite distinct to that under the completeness check: as a first step, the Agency conducts the compliance check, based on the criteria listed in Article 41(1) REACH, and drafts thereupon a decision, specifying whether the applicant complied with the requirements and/or conditions set out in the REACH Regulation or not.²³⁶ Thereafter, the Agency has to resort to the decision-making procedure outlined in Article 51 of the REACH Regulation: according to this procedure, the Agency notifies its draft decision to the national competent authorities (NCAs) of all Member States. Eventually, the NCAs may propose amendments to the draft decision.²³⁷ If no amendments are proposed, the draft decision is to be adopted

²³⁴ Ibid., Articles 20(5) and 91(1).

²³⁵ Criteria for applications falling under the compliance check are listed in Article 41(5) REACH Regulation.

²³⁶ REACH Regulation, Article 51(3).

²³⁷ Ibid., Article 51(1) and (2).

by the Agency without any involvement of the Commission.²³⁸ If, however, amendments are proposed, an amended draft decision is referred to the Member State Committee.²³⁹

The procedure that follows is not only the most innovative part of ECHA's decision-making process, but also explains the, until now, rather mysterious existence of the Member State Committee: after referral to the Committee, the Agency informs registrants and downstream users of any amendments proposed by the NCAs and gives them the possibility to comment within 30 days.²⁴⁰ Any comments received must be taken into consideration by the Member State Committee, which is given 60 days to reach an unanimous agreement on the draft proposal; if the Committee succeeds, the Agency has to adopt the decision accordingly, without any involvement of the Commission.²⁴¹ If, however, the Member State Committee fails to reach unanimous agreement, the matter is referred to the Commission, which adopts the decision according to Article 5 of the Comitology decision (i.e. the regulatory procedure).²⁴²

²³⁸ Ibid., Article 51(3).

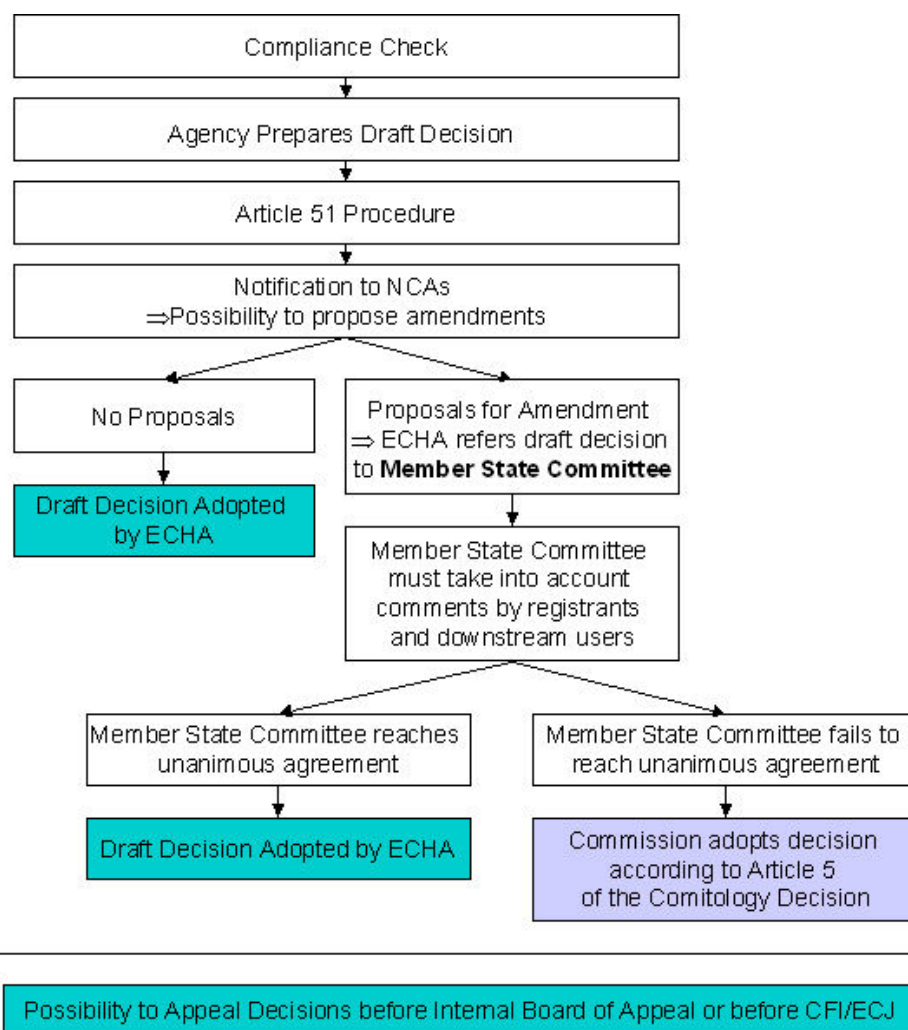
²³⁹ Ibid., Article 51(4).

²⁴⁰ Ibid., Article 51(5).

²⁴¹ Ibid., Article 51(6).

²⁴² Ibid., Article 51(7).

Figure 8: Compliance Check



The decision-making process under Article 51 can thus be said to imply the active involvement of the Member States, through their ability to comment on the draft decision of ECHA, and through their representation in the Member State Committee. Only if the Member States agree with ECHA’s proposal, meaning that either no amendments are proposed or the Committee manages to reach an unanimous agreement on the amended draft decision, is the Agency allowed to adopt the decision. If, by contrast, the Member States disagree, the Agency is deprived of its decision-making power and the authority to take the decision is conferred on the Commission. This means that, different to the registration process of trade marks, the Commission might, under the aforementioned circumstances, still be involved in the registration of chemicals.

IV.3.2 Substance Evaluation

Within the substance evaluation procedure, ECHA plays, as it has been mentioned beforehand, an important co-ordinating role. First of all, the Agency is responsible for the adoption of the EC rolling action plan, according to which seemingly dangerous substances are allocated to the different NCAs for detailed evaluation.²⁴³ The plan's adoption is carried out on the basis of specified criteria listed in Article 44(1) REACH, and only after having consulted the Member State Committee.²⁴⁴ What appears remarkable is that once the substances have been evaluated by the respective national authorities, the draft decisions proposed by the NCAs are referred back to ECHA.²⁴⁵ The Agency is now able to adopt the decision under the Article 51 procedure, the same procedure used with respect to the compliance check (see Figure 8).²⁴⁶ This means that under certain circumstances, ECHA may, even though under the supervision of the Member States (resp. the Member State Committee), take independent decisions at the risk management stage.

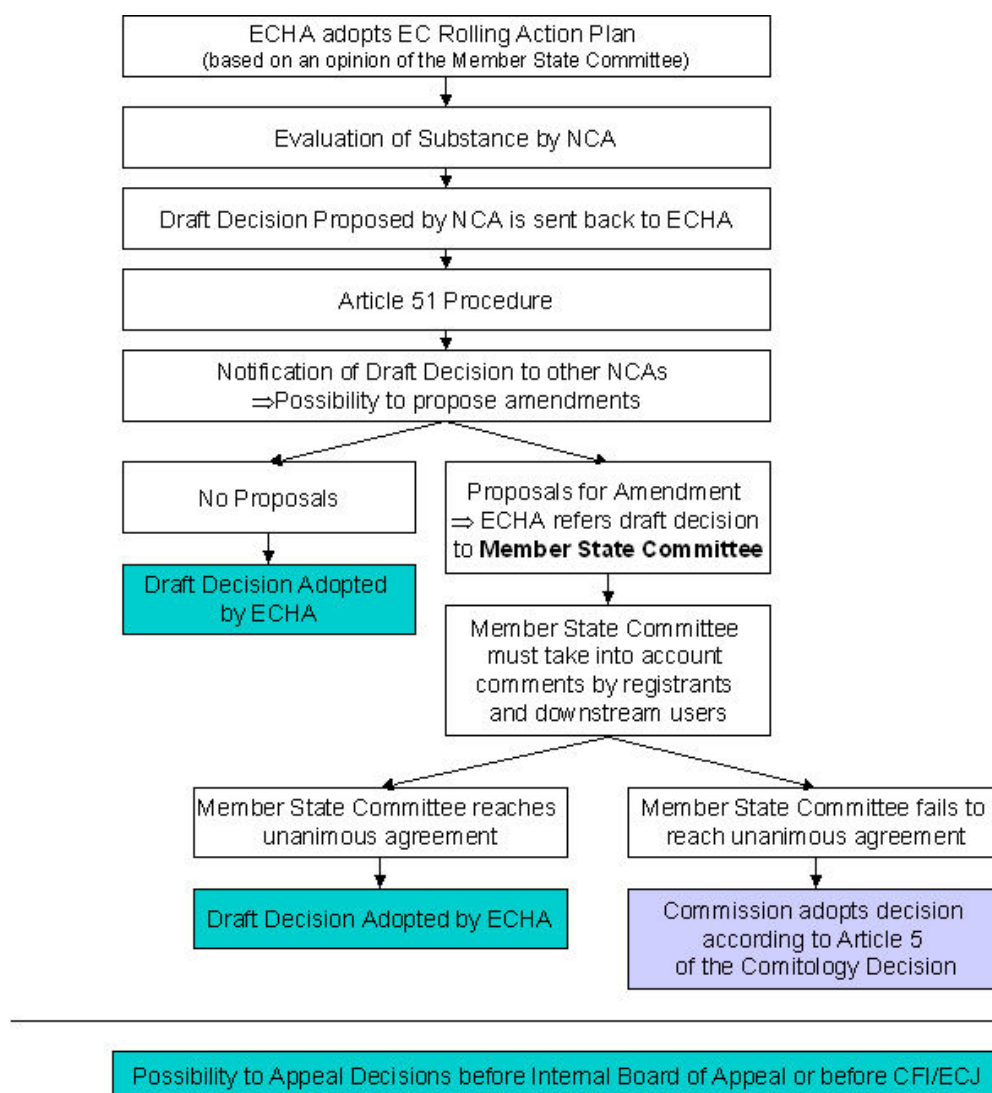
²⁴³ Hanson and Blainey 2006, loc. cit. n. 143, at p. 276.

²⁴⁴ REACH Regulation, Article 44(2).

²⁴⁵ Ibid., Article 52(1). Cf. Hanson and Blainey 2006, loc. cit. n. 143, at p. 276.

²⁴⁶ REACH Regulation, Article 52(2). See Calliess and Lais 2005, loc. cit. n. 134, at p. 294.

Figure 9: Substance Evaluation Procedure



IV.3.3 Authorisation Phase

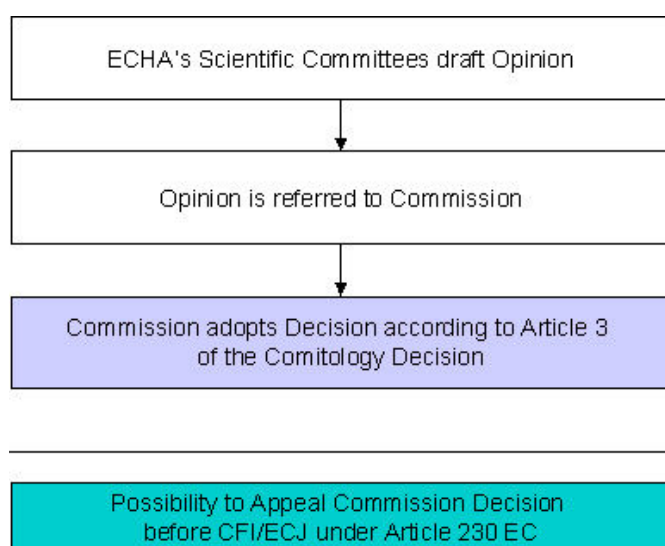
The Agency's role within the authorisation procedure is similar to that of EFSA and EMEA mainly focused on the drafting of scientific opinions. Different to the registration and evaluation stage, it is not allowed to take decisions on applications for authorisation itself, but refers an opinion to the Commission, which eventually adopts the decision in accordance with Article 3 of the Comitology decision (i.e. advisory procedure).²⁴⁷

At this point a side note appears necessary: as just noted, according to Article 64(8) of the REACH Regulation, the Commission adopts the decision to authorise a substance of very high concern by following the advisory procedure, which merely requires the consultation of the comitology committee. This fact seems striking as the Comitology Decision states in Recital 7 that “the regulatory procedure should be followed as regards

measures of general scope designed to apply essential provisions of basic instruments, including measures concerning the protection of the health or safety of humans, animals or plants [...]”.²⁴⁸ Beyond doubt, the authorisation of a substance of very high concern can be described as a “measure concerning the protection of the health or safety of humans, animals or plants”. Therefore, one might doubt whether the choice of the advisory procedure for the adoption of such a decision complies with the Comitology Decision.

Coming back to ECHA’s decision-making powers at the authorisation stage, the Agency is furthermore involved in the preparation of the dossier for “substances of very high concern” (i.e. substances that are subject to the authorisation requirement).²⁴⁹ The decision to include a new substance on a candidate list for possible substances of high concern is taken in accordance with a procedure resembling that of Article 51: hereunder, the agency identifies the substance allegedly being of ‘high concern’ based on criteria outlined in Article 57. This proposal is then circulated to all Member States.²⁵⁰ If no comments are made, the Agency has to include the substance in a candidate list.²⁵¹ If comments are made, the proposal is to be referred to the Member State Committee, which strives to reach an unanimous agreement. If the Member State Committee fails to come to an unanimous opinion, the matter is referred to the Commission, which takes the decision in accordance with Article 5 of the Comitology Decision (i.e. regulatory procedure).²⁵²

Figure 10: Authorisation Procedure



²⁴⁷ Ibid., Article 64(8).

²⁴⁸ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1999] OJ L 184/23.

²⁴⁹ REACH Regulation, Article 59.

²⁵⁰ Ibid., Article 59(3).

²⁵¹ Ibid., Article 59(6).

IV.3.4 Analysis of Findings

In order to analyse the nature of the previously described decision-making powers of ECHA and to provide an informative basis for answering questions concerning those powers' compatibility with the *Meroni* anti-delegation doctrine, it will prove necessary to differentiate between those decisions the Agency is, in any case, able to take independently from the Commission, and those which might lead to the involvement of the Member State Committee and the Commission (coined by the Article 51 procedure; cf. Figure 8 and 9).

With respect to those decisions the Chemicals Agency is allowed to take without any involvement of the Commission, namely the completeness check within the registration procedure and the adoption of the EC rolling action plan at the evaluation stage, it became obvious that these decisions have to be based on clear criteria, defined in the REACH Regulation.²⁵³ Therefore, this kind of decisions cannot be described as discretionary but has to be seen as purely implementary in nature. Referring back to the question of whether ECHA's decision-making powers are still compatible with the *Meroni* doctrine, the answer has to be in the affirmative.

More interesting is of course the second category of decisions, whose adoption might imply, in certain circumstances, the involvement of the Member State Committee and the Commission. The decision-making procedure under Article 51 (or one resembling that; cf. Figure 5) is used in three different situations: first, when conducting the compliance check as part of the registration process; second, when adopting the draft decision prepared by an NCA on the evaluation of a substance; and, finally, when identifying 'new' substances of very high concern for a candidate list which is eventually decided upon by the Commission. Can these decisions still be considered as being purely implementary in character, or do they contain discretionary elements? According to the Oxford English Dictionary, discretion is to be defined as "the freedom to decide what should be done in a particular situation".²⁵⁴ With respect to the first situation, the compliance check, Article 41(1) of the REACH Regulation lists detailed information on how this examination shall be conducted and which criteria are to be taken into consideration. Therefore, it cannot be concluded that there is 'freedom' left to ECHA in taking the decision. Similarly, also the decision on the identification of substances of very high concern has to be grounded on clearly defined criteria, which are listed in Article 57. Furthermore, the Agency only determines which substances are to be

²⁵² Ibid., Article 50(9). See also Hanson and Blainey 2006, loc. cit. n. 143, at p. 277.

²⁵³ The criteria according to which the completeness check is to be conducted are listed in Article 20(2) of the REACH Regulation; those according to which the EC rolling action plan should be drafted are specified in Article 44(1).

²⁵⁴ AskOxford (2008) *Discretion*, available at: <http://www.askoxford.com/concise_oed/discretion?view=uk>.

added to a candidate list; the final decision on the inclusion of new substances of very high concern stays with the Commission.

Less clear cut, however, is the question of whether the adoption of the draft decision prepared by the NCAs under the substance evaluation procedure may be described as ‘discretionary’. Recalling the criteria for the establishment of regulatory agencies, which are ultimately based on the *Meroni* conditions of 1958 (cf. Chapter II.3), the White Paper on European Governance interdicts, *inter alia*, the agencies’ arbitration between different public interests as this would result in a ‘discretionary’ decision, thus disturbing the Union’s ‘institutional balance’.²⁵⁵ Within the substance evaluation procedure, it was shown that ECHA is not involved in the evaluation itself; it has no discretion to decide on the content of the draft decision and the decision to adopt the draft is taken automatically by the Agency once there is no objection on part of the Member States. However, in case no Member State authority objects, the Agency adopts an NCA’s evaluation, hereby classifying a substance either as dangerous (i.e. subjecting it to authorisation) or as innocuous (i.e. not subjecting it to authorisation). But what about concerned consumer organisations disagreeing with an ECHA’s decision classifying a substance as innocuous? What about the industry which fears financial losses when classifying a substance as dangerous? Are there not different public interests at play?

Certainly, the decision to classify a substance either as dangerous or innocuous *is* a policy decision, as it implies a balancing act of different public interests such as, for example, the protection of human health, on the one hand, and the competitiveness of the European economy, on the other. Therefore, the Agency’s involvement in the substance evaluation process contradicts the Commission’s statement in its White Paper on European Governance which, in turn, functions to implement the anti-delegation principle established in the *Meroni* judgments of 1958.²⁵⁶ Consequently, there is well-founded reason to question the compatibility of these decision-making powers of ECHA with the *Meroni* doctrine. Equally striking, it is not the Commission’s preparation by which ECHA is bound within the substance evaluation, but it adopts a decision completely drafted by a national competent authority; this is highly unusual, because normally it is the Agency who would prepare a draft decision which is eventually adopted by the Agency itself or, in case of Agencies without decision-making powers, by the Commission (cf. OHIM, EFSA, EMEA). Within ECHA, a completely new mode of delegation emerges and one may doubt whether this

²⁵⁵ European Commission 2001, see *supra* n. 45, at p. 24; European Commission 2005, see *supra* n. 35, at p. 11; *Meroni*, see *supra* n. 6, at para. 152.

²⁵⁶ Vos and Wendler 2006, loc. cit. n. 198, at p. 76.

mode may still be defined as falling under the anti-delegation framework. At least, this new form of delegation hollows out a restrictive interpretation of the 1958 *Meroni* judgments.

Apart from these far-reaching conclusions, it has to be noted that ECHA's ability to adopt the NCAs' draft decisions adds considerably to the efficiency of the new EU chemicals policy: time-consuming referrals of decision-making authority to the Commission are avoided. This is particularly relevant regarding the registration of 30.000 existing substances which awaits the Chemicals Agency in its first years of operation. Only in case of disagreement does the Member State Committee act as a 'safety valve', able to refer controversial decisions back to the Commission. The Committee's existence makes it possible for ECHA to take decisions, such as the above-mentioned adoption of the NCAs' draft decisions, which would have been otherwise directly referred to the Commission. Yet, is its function really new?

Recalling the discussion in Chapter IV.1.4, also EFSA's Advisory Forum has a mandate to resolve conflicts between EFSA and national food authorities where a "substantive divergence over scientific issues has been identified" and it was questioned why the functions of EFSA's Advisory Forum were split into two organs, i.e. into the Forum and the Member State Committee, within ECHA's structure.²⁵⁷ Realising now the Member State Committee's essential role in ECHA's decision-making process, the split of functions becomes plausible: because ECHA disposes of decision-making powers, the Member State Committee, when exercising its mandate, really *decides* upon 'controversial opinions'. By contrast, in EFSA's Advisory Forum this mandate results in a completely different task, as the Agency does not dispose of decision-making powers and the Advisory Forum may only encourage the resolution of controversial opinions by a closer co-operation between the national authorities and EFSA. On the one hand, the split of functions enables ECHA's Member State Committee to focus exclusively on its important role in the decision-making process; on the other hand, the focus on only one task enormously enhances the transparency of the Committee's work and ultimately that of the whole decision-making process.

Yet, taking a glance *beyond* European agencies, one might stumble across another function comparable to that of the Member State Committee in ECHA, namely across that of the much discussed comitology procedure.²⁵⁸ As it is well-known, the Commission has been conferred implementing powers by the Council, and potentially by the EP under the

²⁵⁷ General Food Law, Articles 27(4b) and 30(4).

²⁵⁸ Cf. Council Decision 1999/468 of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1999] OJ L 184/23.

co-decision procedure.²⁵⁹ But, instead of providing the Commission with a *carte blanche* in exercising these powers, the Council enacted a control mechanism, achieved through a committee system called ‘comitology’.²⁶⁰ Hereunder, the draft decisions must either be discussed (cf. advisory procedure) or even be approved (cf. regulatory procedure) by a committee, composed of national bureaucrats appointed by the Member States and chaired by a representative of the Commission.²⁶¹ That way, the Commission is controlled in its implementing powers by the Member States. Could the Member State Committee’s role in ECHA’s decision-making process not be described in the same way, yet taking place at a different level?

A closer look at the composition of the Member State Committee²⁶² reveals that, just like the comitology committees, the Member State Committee consists of national bureaucrats, specialised in a field relevant to the work of ECHA,²⁶³ and who are overwhelmingly employed in national ministries for health, environment or consumer protection, in national chemicals agencies or in other public services.²⁶⁴ Yet, different to the composition of the comitology committees, which are chaired by a Commission representative, the Member State Committee is not chaired by an Agency representative. The committees’ role, however, resembles each other to a striking extent: both committees control the decision-making process of an agent, hereby avoiding the conferral of a *carte blanche* to the agent in the exercise of its functions. Consequently, it is possible to argue that the establishment of both kinds of committees was motivated by the same idea.

Moreover, the decision-making procedure outlined in Article 51 (cf. Figure 6 and 7) encourages to a remarkable extent the co-operation between ECHA, the Member States, and the Commission, the result of which can be regarded as a ‘common decision’ that ameliorates ECHA’s networking capacity and leads to an increased collaboration at EU level, in the ideal case even to a higher enforcement rate at national level. Furthermore, the extensive involvement of the Member States may also be seen as an expression of the principle of subsidiarity, which is consolidated in Article 5 of the EC Treaty and stipulates that “the Community shall take action only insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, [...], be better

²⁵⁹ Lenaerts and van Nuffel 2005, op. cit. n. 29, at p. 614.

²⁶⁰ Ibid.

²⁶¹ Ibid., at pp. 615-617.

²⁶² List of Members of Member State Committee, available at:

<http://echa.europa.eu/about/organisation/committees/ms_members_en.asp>.

²⁶³ Ibid. The majority of members of the Member State Committee has a background in chemistry, chemical engineering, biology or environmental sciences; only two members have a background in law and economics.

²⁶⁴ Ibid.

achieved by the Community”.²⁶⁵ Generally, the principle is seen to fulfil a “filter function” between Community and national competence.²⁶⁶ This is supported when having a look at Recital 67 of the REACH Regulation which declares that the “[c]ollective agreement within the Agency’s Member State Committee on its draft decisions should provide the basis for an efficient system that respects the principle of subsidiarity, while maintaining the internal market”.

Finally, it became clear that the most important decision (in the sense that a ‘wrong’ decision might have the most serious consequences, for human health and the environment), namely the authorisation of “substances of very high concern”, stays completely with the Commission. Here, ECHA only acts as an advisory body, like the existing regulatory agencies involved in risk regulation, EFSA and EMEA.

IV.4 Conclusion

This Chapter revealed particularities and innovations in the Chemicals Agency’s structure, tasks and decision-making process that are not only necessary but also worth summarising. With respect to ECHA’s organisational structure, it has been found out that, paradoxically, its design is closer to that of the classical regulatory agency, without decision making-powers, than to that of the Trade Mark Office, with decision-making powers. The only organ that can be found in OHIM’s and ECHA’s composition alike is the Board of Appeal. Completely new in ECHA’s design is the Member State Committee which, as it became clear above, occupies a major role in the Article 51 decision-making process. None of the existing agencies, with or without decision-making powers, features a comparable organ exclusively fulfilling the conciliation function (cf. EFSA’s Advisory Forum).

ECHA is, furthermore, involved in an unusual high number of different functions as it occupies an important role in *each* step of the risk regulation process. This is notable given the fact that EFSA and EMEA are only allowed to be involved in the risk assessment and not in the risk management process in order to guarantee a strict separation between politics and scientific work, on the one hand, and to avoid the involvement of the Agency in the balancing of public interests at the risk management stage, on the other. The analysis revealed that the Chemicals Agency’s role in the risk management process conflicts with the old established rules, ultimately based on the *Meroni* conditions of 1958, as it might hereby

²⁶⁵ Article 5 EC.

²⁶⁶ Lenaerts and van Nuffel 2005, op. cit. n. 29, at p. 101.

be involved in the conciliation of conflicting public interests as prohibited by the White Paper on European Governance.²⁶⁷

Most distinctive and innovative is ECHA's decision-making process. Whereas until ECHA's establishment, having decision-making powers and not having decision-making powers was seen as a black-or-white issue (i.e. either an agency had them or not), the creation of ECHA introduced a more differentiated alternative. Except for the completeness check and the adoption of the EC rolling action plan, ECHA's (independent) decision-making powers under Article 51 can only be exercised under particular circumstances. Once a Member State proposes (an) amendment(s) to a draft decision, the Member States Committee intervenes, which has to give its unanimous agreement before the Agency can proceed and adopt the decision. In case of no agreement on the controversial matter, the decision is automatically referred to the Commission. The role of the Member State Committee has been compared to that of the comitology committees within the Commission's executive powers; both, the comitology committees, on the one hand, and ECHA's Member State Committee, on the other, perform a control function, depriving their agents of a *carte blanche* in the decision-making process. Finally, it has been observed that the Committee's involvement necessitates and promotes the interaction and collaboration between ECHA, Member States and Commission, thus respecting the principle of subsidiarity.

V – Holding the European Chemicals Agency Accountable

Section 4 of Chapter II related European Agencies to the emerging multi-level structure of European Governance. It deduced that such a 'new' form of governance (as opposed to the 'traditional' national democratic structure) also requires additional forms of accountability; 'traditional' forms of accountability, based on a direct chain of delegation (voter-legislature-agency), could not properly work at European level. This deficiency was mainly attributed to the existence of multiple principals (including forums at national and European level), effecting a complex web of accountability relations at European level. Generally, it was concluded that, so far, the existing mechanisms are unable to hold European agencies sufficiently to account.

²⁶⁷ See *supra* n. 35, p. 11.

Drawing on this earlier discussion, this Chapter will apply the aforesaid forms of accountability to ECHA and examine whether the findings of the previous Chapter, namely ECHA's particular structure, tasks and decision-making processes, enhance the principals' control over the Agency. In doing so, comparative account will again be taken of existing agencies, with and without decision-making power.

V.1 'Traditional' Forms of Accountability

Chapter II identified *democratic accountability* as the main 'traditional' form of accountability, with the agent, i.e. the agency, being held accountable before a representative institution. Yet, it was also noticed that so far democratic accountability was hardly able to work at European level because the European Parliament, as the only truly European representative institution, does neither always act as a principal nor does it dispose of strong supervisory powers. Thus, could ECHA's design enhance the EP's oversight?

Unlike the Trade Mark Office, which is based on Article 308 EC, the European Chemicals Agency is founded on Article 95 EC. Eventually, the EP has been involved, through the co-decision procedure, in the establishment of ECHA, which is reflected also in the Agency's design: in contrast to OHIM's Administrative Board, ECHA's Management Board hosts two persons appointed by the EP.²⁶⁸ Furthermore, ECHA's Executive Director is, before being appointed, "invited as soon as possible to make a statement before the EP and to answer questions from Members of Parliament".²⁶⁹ No such provision exists in the Trade Mark Regulation as OHIM's President is directly elected by the Council.²⁷⁰ In addition thereto, the European Parliament may exercise significant control over ECHA's budget, since ECHA is partly dependent on Community subsidies which the EP is able to oversee as non-compulsory expenditure.²⁷¹ By contrast, OHIM is financially self-sufficient.²⁷² Consequently, the EP's control over the Chemicals Agency is by far greater than its (marginal) oversight of the Trade Mark Office.

Yet, when comparing the EP's involvement in ECHA to that in EFSA or EMEA, no improvement in the EP's supervisory powers can be noticed. Like ECHA, the two agencies were established according to the co-decision procedure; EMEA's Management Board also

²⁶⁸ REACH Regulation, Article 79.

²⁶⁹ *Ibid.*, Article 84(1).

²⁷⁰ Trade Mark Regulation, Article 120(1).

²⁷¹ Vos 2003, loc. cit. n. 3, at p. 137. REACH Regulation, Article 96. The other part consists of revenues from fees for the registration and authorisation of chemicals paid by the industry.

²⁷² Trade Mark Regulation, Article 134(3).

includes two representatives of the EP,²⁷³ and both constituent regulations require the Executive Director to answer questions posed by Members of Parliament before taking his/her office.²⁷⁴ Furthermore, the EP has the power to oversee EFSA's and EMEA's budgets as both agencies are, like ECHA, partly dependent on Community subsidies.²⁷⁵ Eventually, it can be said that even though the EP is better represented in ECHA's structure than in that of OHIM, nothing improved in comparison to the already existent regulatory agencies EMEA and EFSA; the Parliament's oversight remains deficient.

V.2 Additional Forms of Accountability

The second Chapter identified six types of oversight mechanisms falling under the category of additional forms of accountability; these forms comprise: accountability through legislation, Member State accountability, financial and judicial accountability, social accountability as well as administrative accountability.²⁷⁶

Each of them will be applied to ECHA in turn; however, the first form of accountability, namely accountability through legislation, will only be shortly mentioned: the previous Chapter indicated that both ECHA's and OHIM's constituent regulations list clear criteria based on which decisions are to be taken. Therefore, a more detailed examination of this first form seems redundant. Yet, what seems novel in ECHA's constituent regulation are the extensive reporting requirements. Whereas all constituent regulations²⁷⁷ contain articles requiring the Management Board, Executive Director or President to forward the agencies' work programmes and general activity reports to the Commission,²⁷⁸ only the REACH Regulation includes an additional Article 117 named 'reporting'. Under this Article, ECHA must submit to the Commission, in addition to the 'normal' reporting requirements, a general report on the Regulation's operation every five years.²⁷⁹

²⁷³ EMEA Regulation, Article 65.

²⁷⁴ EMEA Regulation, Article 64(1); General Food Law, Article 26(1).

²⁷⁵ EMEA Regulation, Article 43(1); General Food Law, Article 67(3).

²⁷⁶ See Chapter II.4.

²⁷⁷ I.e. that of EFSA, EMEA, OHIM, EASA and ECHA.

²⁷⁸ REACH Regulation, e.g., Article 83; Trade Mark Regulation, Article 119; EASA Regulation, Article 33(2c); General Food Law, Article 26(3); EMEA Regulation, Article 65.

²⁷⁹ REACH Regulation, Article 117(2).

V.2.1 Member State Accountability

Most interesting with respect to ECHA's particular structure and decision-making process is the Member State control. As it became clear in the preceding Chapter, the Chemicals Agency's organisational structure is in many respects very close to that of the classical regulatory agency (and thus to that of EASA); consequently, its Management Board is, like that of EMEA and EASA, composed of Member State representatives, enabling them to oversee the Agency's activities.²⁸⁰ For means of comparison, OHIM's Administrative Board also consists of Member State representatives; nevertheless, their control is limited due to the Administrative Board's overall restricted role.²⁸¹

Of high relevance is the Member State Committee in ECHA's structure whose role and function have been compared to that of the comitology committees within the Commission's decision-making process.²⁸² Recalling the Article 51 procedure, Member States may propose amendments to any draft decision prepared by ECHA, which in turn leads to the involvement of the Member State Committee and, in case of controversial decisions, even to that of the Commission (cf. 'safety valve' function of the Member State Committee). Eventually, the Member States control – one may even say dominate – to a considerable extent the Article 51 decision-making process.

Comparing the registration processes of OHIM and ECHA, it became clear that OHIM's registration procedure and the completeness check within ECHA's registration process resemble each other; both processes work without the involvement of Member States or Commission. However, ECHA's registration process may in addition to the completeness check also include the more extensive compliance check. Unlike the completeness check, the compliance check is subject to the Article 51 procedure and may thus lead to the involvement of Member States and Commission.²⁸³ Consequently, an interference of Member States and Commission cannot be excluded in ECHA's registration process. Hence, one has to deduce that the Chemicals Agency's registration process is subject to a closer control than that of OHIM.

V.2.2 Financial Accountability

Switching over to the next form of accountability, namely financial accountability, the second Chapter identified three (potential) mechanisms of an agency's budgetary control: first, the budgetary power enjoyed by the EP over non-compulsory expenditure; second, the

²⁸⁰ REACH Regulation, Article 79(1); EMEA Regulation, Article 65.

²⁸¹ See Chapter II.1; Trade Mark Regulation, Article 122(1).

²⁸² Cf. Chapter IV.3.

supervision by the Court of Auditors (cf. Article 248 EC); and, finally, inspections conducted by the European Anti-Fraud Office (OLAF).

The budgetary powers of the EP have already been discussed under democratic accountability: here, it became clear that whereas ECHA, EMEA and EFSA are subject to the EP's budgetary oversight as they are partly dependent on EC subsidies, the self-sufficient Trade Mark Office is not. Similarly, with respect to the other two mechanisms, i.e. the oversight by the Court of Auditors and the European Anti-Fraud Office, ECHA, EMEA and EFSA provide for analogue provisions, allowing the two aforesaid EU organs to oversee their budgets.²⁸⁴ OHIM, on the contrary, only provides for a provision allowing the Court of Auditors to control the Agency's revenues and expenditures;²⁸⁵ the Anti-Fraud Office does not seem to have any powers with respect to OHIM. Hence, it can be concluded that the Chemicals Agency is subject to the same financial control mechanisms as EFSA and EMEA, which is due to the fact that all three agencies are partly dependent on the Community budget and therewith fall under different control mechanisms than the self-sufficient Trade Mark Office.

V.2.3 *Judicial Accountability*

Discussing the judicial accountability of the Chemicals Agency, it appears necessary to distinguish between the legal review of decisions taken by the Agency itself, and the review of scientific opinions which are only prepared by ECHA but have to be formally adopted by the Commission.

The judicial review of decisions *adopted* by ECHA appears rather uncomplicated: like decisions taken by OHIM and EASA, decisions taken by the Chemicals Agency may be contested before the agencies' internal Boards of Appeal.²⁸⁶ If the appellant also opposes the decision taken by the Boards of Appeal, all three agencies provide for the possibility to bring a further action before the CFI or the ECJ under Article 230 EC.²⁸⁷ Problems, however, arise when non-privileged natural or legal persons object to an Agency's decision. As it is the case with the legal standing of individuals before the ECJ or the CFI, those non-privileged applicants have to prove that they are directly and individually concerned by the

²⁸³ Cf. Chapter IV.3.

²⁸⁴ REACH Regulation, Articles 97(4) and 98(2); General Food Law, Articles 55(9) and 44(3); EMEA Regulation, Articles 69 and 68(3).

²⁸⁵ Trade Mark Regulation, Article 137(1).

²⁸⁶ REACH Regulation, Article 91; Trade Mark Regulation, Article 130; EASA Regulation, Article 40(1).

²⁸⁷ REACH Regulation, Article 94; Trade Mark Regulation, Article 63(1); EASA Regulation, Article 50. See also van Ooik 2007, loc. cit. n. 10, at pp. 147/148.

Agency's decision or, put differently, they have to pass the "Plaumann test".²⁸⁸ This is difficult, e.g., for consumer organisations which normally cannot prove their direct and individual concern and, thus, have no legal standing – neither before the ECHA's Board of Appeal nor before the CFI or the ECJ.

Problematic is also the legal review of opinions drafted by agencies which become legally binding upon third parties only after formal adoption by the Commission. The preceding Chapter has shown that within the authorisation stage of REACH, the Chemicals Agency is responsible for the preparation of scientific opinions, advising the Commission whether a certain substance should be authorised or not; yet, the actual decision can only be taken by the Commission.²⁸⁹ Consequently, the same problems emerge as with respect to scientific opinions drafted by EFSA and EMEA: firstly, the opinions prepared by ECHA's scientific committees cannot be directly reviewed by the Community Courts.²⁹⁰ Furthermore, the judges' lack of expertise on chemistry and biology makes it almost impossible for them to assess the correctness of the scientific data on which ECHA's opinions are based.

V.2.4 Social Accountability

Social accountability was defined as relating to the control of agencies by civil society and the inclusion of agencies into networks of national authorities. The control by civil society includes the participation of stakeholders and interested parties into the agencies' work and decision-making processes. Thus, to what extent are stakeholders able to participate in ECHA's activities?

First of all, ECHA's Management Board includes, as mentioned in the previous Chapter, three observers (i.e. no voting rights) from interested parties.²⁹¹ However, this is nothing new when compared to EMEA, whose Management Board hosts four members from stakeholder organisation.²⁹² Also the unusual composition of EFSA's Management Board comprises four members having a background in consumer or other food related organisations.²⁹³ By contrast, novel is the fact that the REACH Regulation contains provisions allowing stakeholders to attend meetings of all Committees and the Forum upon

²⁸⁸ Case C-25/62 *Plaumann* [1963] ECR 95, establishing the "Plaumann test" for non-privileged applicants before the Community Courts; cf. REACH Regulation, Article 92(1), stating that "any natural or legal person may appeal against a decision addressed to that person, or against a decision which [...] is of direct and individual concern to the former". See also Geradin and Petit 2004, loc. cit. n. 23, at p. 51.

²⁸⁹ Cf. Chapter IV.3.

²⁹⁰ *Olivieri* Case, see *supra* n. 107; and *FMC Chemicals v. EFSA*, see *supra* n. 108.

²⁹¹ REACH Regulation, Article 79(1).

²⁹² EMEA Regulation, Article 65(1).

invitation by Committee members or the Management Board,²⁹⁴ no such explicit provisions exist in the constituent regulations of the other three agencies. Remarkable is also the possibility for registrants and downstream users to comment on the amended draft decision presented to the Member State Committee under ECHA's Article 51 decision-making procedure.²⁹⁵ This allows stakeholders to participate, albeit indirectly, in ECHA's decision-making process. Finally, the REACH Regulation includes an Article 108, which is exclusively devoted to "contacts with stakeholders" and calls upon the Management Board to develop ties between the Agency and "relevant stakeholder organisations". Eventually, it can be deduced that ECHA's drafters took further steps towards greater public participation in ECHA's work.

The umbrella term of 'social accountability' also encompasses the involvement of an agency into networks of relevant national authorities, which are able to exert additional pressure on the Agency. Certainly, all agencies discussed maintain close contacts to respective national authorities; yet, there are two particularities in ECHA's structure and procedures that result in an additional strengthening of its network functions: first, ECHA disposes of the Forum whose task is the close collaboration with national authorities in order to enhance the harmonised enforcement of an EU chemicals policy.²⁹⁶ No such organ exists in OHIM's or EMEA's structure, but only in that of EFSA.²⁹⁷ Second, the Member States' active involvement in ECHA's decision-making procedure under Article 51 has the positive side-effect of fostering liaison between ECHA, Member States and Commission.

Next to the just mentioned institutional provisions, transparent rules and access to an Agency's documents were identified as further indispensable prerequisites for public participation. On the one hand, transparent rules necessitate the existence of clear rules of procedure and a statement of reasons for any decision taken. Yet, nothing new can be observed when comparing ECHA's rules to those of OHIM, EMEA and EFSA: all constituent regulations require the Management (resp. Administrative) Boards to adopt rules of procedure;²⁹⁸ furthermore, the REACH Regulation and the Trade Mark Regulation require the Commission to adopt rules of procedure for the agencies' Boards of Appeal;²⁹⁹ also, the two regulations provide for similar articles obliging the agencies to state reasons

²⁹³ General Food Law, Article 25(1).

²⁹⁴ REACH Regulation, Articles 85(4) and 86(1).

²⁹⁵ *Ibid.*, Article 51(5).

²⁹⁶ Cf. Chapter IV.1.

²⁹⁷ Cf. Chapter IV.

²⁹⁸ REACH Regulation, Article 78; Trade Mark Regulation, Article 124(4); EMEA Regulation, Article 65(7); and, General Food Law, Article 25(5).

²⁹⁹ REACH Regulation, Article 93(4); Trade Mark Regulation, Articles 157(3) and 158(3).

for all their decisions taken.³⁰⁰ On the other hand, ECHA, like OHIM and EMEA, is subject to Regulation (EC) No 1049/2001 on the public access to documents.³⁰¹ And, while most existing agencies already make publicly available a large part of their documents over the internet, this practice is now consolidated in ECHA's Article 119 on 'electronic public access'.

V.2.5 Administrative Accountability

Administrative accountability was identified as referring to checks and balances incorporated in the European administrative structure, with the most notably example at European level being the European Ombudsman, who is able to investigate into cases of maladministration by the EU institutions or organs.³⁰² Like the Trade Mark Regulation and EMEA's constituent regulation, also the REACH Regulation allows the European Ombudsman to file a complaint concerning decisions taken by the Agency in the context of Regulation (EC) No 1049/2001 on the public access to EU documents.³⁰³ Hence, no noticeable improvements took place.

V.3 Conclusion

This Chapter aimed to reveal changes in the principals' control over the European Chemicals Agency, effected through the Agency's particular structure and decision-making process, in comparison to that over the already existent agencies. The most relevant findings are briefly summarised below.

The first finding to be made was that no improvement could be noticed with respect to the traditional form of accountability, namely ECHA's democratic accountability, in comparison to that of EMEA and EFSA. Regarding the EP's hitherto limited supervision powers, this result is all but surprising. Turning to the new forms of accountability, noticeable findings could be made with respect to Member State, judicial and social accountability. Of the said forms, the most important improvements in control over ECHA were found under the heading of 'Member State accountability'.

³⁰⁰ REACH Regulation, Article 130; Trade Mark Regulation, Article 73.

³⁰¹ REACH Regulation, Article 118(1); Trade Mark Regulation, Article 118a(1); EMEA Regulation, Article 73.

³⁰² Cf. Bovens 2007, loc. cit. n. 85, at p. 110.

³⁰³ REACH Regulation, Article 118(4); Trade Mark Regulation, Article 118a(3); EMEA Regulation, Article 73.

Firstly, it was discovered that because ECHA's structure is in many respects closer to that of the classical regulatory agency than to that of OHIM, Member States are able to exert considerable control over the Agency through the Management Board. Secondly, the unique role of the Member States in ECHA's Article 51 decision-making procedure cannot be overestimated: through the involvement of national authorities, on the one hand, and the Member State Committee, on the other, the decision-making process was found to be largely dominated by the Member States. Comparing OHIM's and ECHA's registration processes, it was revealed that ECHA's registration process may in contrast to the completely independent registration process of OHIM lead to the interference of the Member States and, in some circumstances, even to that of the Commission. Therefore, it can be concluded that the Chemicals Agency is subject to a considerably tighter Member State (and Commission) control than the Trade Mark Office.

The 'accountability gap' that is said to exist with respect to opinions drafted by EMEA and EFSA could not be filled with the new Chemicals Agency. Just as the opinions prepared by EMEA and EFSA, also those drafted by ECHA during the authorisation procedure of chemicals of very high concern cannot be challenged before the Community Courts. Consequently, there is no possibility to hold the Agency directly responsible for the contents of its opinions.

Interesting findings were finally made regarding the public participation of interested parties in ECHA's activities. First of all, a novel feature in the REACH Regulation is that it contains additional provisions allowing stakeholders, upon approval, to attend Forum and Committee meetings. None of the existing agencies contains like provisions. Second, the Article 51 decision-making procedure allows registrants and downstream users to comment on the amended draft decision before its adoption. Finally, ECHA is embedded in a particularly close network of national authorities, what can be attributed to the existence of the Forum (co-ordinating contacts with relevant national authorities) and to the unusually extensive involvement of Member States' national authorities in the Agency's decision-making process.

VI – Conclusion: ECHA as Blueprint for Future European Regulatory Agencies?

Returning to the research questions, this Thesis intended to analyse the extent to which the delegation of decision-making powers to the European Chemicals Agency is still compatible

with the anti-delegation doctrine based on the *Meroni* judgments of 1958 and, further, which supervisory mechanisms have been inserted to control the Agency's activities and to hold it accountable for its decisions. The focus of the Thesis was motivated by the European Union's continued adherence to the restrictive conditions of the anti-delegation doctrine, interdicting the delegation of discretionary powers to subordinate EC bodies. Complying with this doctrine, the EC has been extremely cautious in the conferral of decision-making powers to European Agencies. The fact that the European Chemicals Agency was given the power to adopt independent decisions has therefore to be regarded as exceptional, justifying the focus of the Thesis.

To enable a proper reply to the research questions, an introduction not only to the current agency debate but also to the complex of problems inherent in the delegation of powers was inevitable. In order to illustrate the delegation process, the principal-agent framework was used. The framework's application to the European level however revealed difficulties in the identification of clear accountability relations between the principal and its agents, caused by the existence of multiple principals at EU level; in turn, the complex web of accountability relations was found to lead to complications in the agencies' control. The said anti-delegation doctrine was adopted by the Court of Justice as a reaction hereto; the Court claimed that only the preservation of the original institutional balance between Council, Commission and EP could ensure the democratic legitimacy of the European Union. Yet, the Court's doctrine has been heavily criticised for allegedly leading to the directly opposite result, namely to an aggravation of accountability concerns, through the agencies' existence in a "constitutional twilight zone".³⁰⁴

In order to reply to the first research question focussing on the compatibility of the Chemicals Agency's decision-making powers with the *Meroni* doctrine, a detailed analysis not only of ECHA's decision-making powers but also of its organisational structure and tasks proved necessary. The examination revealed the existence of two different categories of decisions: on the one hand, those decisions ECHA is able to adopt independently from Member States and Commission; on the other hand, those which are subject to the Article 51 procedure. The former category was found not to lead to any conflicts with the *Meroni* conditions, as the REACH Regulation provides for clear conditions on which these decisions have to be based, excluding the exercise of 'discretion' on part of ECHA.

Incompatibilities were however detected with respect to the second category. The Article 51 procedure was discovered to be coined by the active participation of the Member

³⁰⁴ Lenaerts and Verhoeven 2002, loc. cit. n. 59, at p. 48.

States; through their national authorities' right to comment on the prepared draft decisions, but also through the potential involvement of the Member State Committee whose "safety valve" function was compared to that of the comitology committees within the Commission. Within the substance evaluation procedure, the Agency has been granted the power to adopt evaluations prepared by the national competent authorities under the Article 51 procedure. It was found that such a decision unambiguously involves a balancing act between different public interests – most likely between public health concerns and the proper functioning of the internal market. The White Paper on European Governance has, however, prohibited the adoption of decisions by agencies that arbitrate between different public interests; such decisions are regarded as being 'discretionary' in nature and thus contrary to the institutional balance of powers.³⁰⁵ *Therefore, the Agency's involvement in the adoption of decisions at the substance evaluation stage conflicts with the anti-delegation principle. The answer to the first research questions must consequently be that the new Chemicals Agency's decision-making powers are only to a certain extent compatible with the Meroni doctrine.*

It follows that the delegation of power to ECHA denotes a departure from the long-established anti-delegation principle. As it became clear, the principle was established to protect the Union's institutional balance; thus, what consequences does the departure imply for the balance of power within the European Union? Self-evidently, any answer to this question conditions an essential intermediate step, namely what does the concept of 'institutional balance' actually mean? Unfortunately, the scope of this concept is far from clear.³⁰⁶ Some scholars have equated the concept with the separation of powers, referring to an organic separation between the legislature, executive and judiciary; such an organic separation is, however, not given at European level, mainly because of the legal basis requirement, which prevents a fixed determination of institutions involved in the legislative process, and the Union's three-pillar structure.³⁰⁷ More suited for the EU's particular structure is therefore the idea of a system of checks and balances, in which each institution represents a different societal interest, controlling each other and preventing the concentration of power in one institution.³⁰⁸ Lenaerts and Verhoeven add that the concept of institutional balance is necessarily evolutionary, adapting itself to the overall development and needs of the European Union.³⁰⁹

³⁰⁵ Vos and Wendler 2006, loc. cit. n. 198, at p. 76.

³⁰⁶ Lenaerts and Verhoeven, loc. cit. n. 59, at p. 35.

³⁰⁷ Ibid., at p. 38.

³⁰⁸ Ibid., at pp. 42 and 43.

³⁰⁹ Ibid., at p. 38.

Yet, the institutional balance as protected by the *Meroni* doctrine is that of 1958. As it became clear in Chapter II.3, scholars like Renaud Dehousse view the anti-delegation principle as long obsolete.³¹⁰ Dehousse goes even so far to argue that the anti-delegation principle has erected a “façade” of EU law behind which the Union’s real functioning lies. In his view, the emergence of agencies must be regarded as part of the Union’s evolution towards a greater decentralisation of administrative tasks in response to new functional needs (cf. the ‘regulatory problem’ of the Commission, Chapter II.1).³¹¹ By formally denying this trend, the doctrine effected a complex of legislation and artificial mechanisms, such as the Commission’s formal adoption of opinions drafted by agencies, eventually leading to serious accountability and legitimacy concerns: for example, who can be held responsible for the Agency’s opinion?

Before continuing this discussion, an answer to the second research question, dealing with the accountability and control of the European Chemicals Agency, seems expedient. In order to do so, the paper intended to unveil improvements or impairments in the Chemicals Agency’s accountability and control, effected by its particular structure and decision-making powers, based on previously defined supervisory mechanisms. Unsurprisingly, the analysis could not reveal any noticeable changes with respect to traditional accountability arrangements, i.e. ECHA’s democratic accountability to and control through the European Parliament. Interesting findings were, however, made under the headings of Member State accountability, judicial accountability and social accountability.

Remarkable improvements in the control over ECHA were discovered when analysing the Member States’ involvement in ECHA’s structure and decision-making procedures. On the one hand, the fact that ECHA’s organisational structure is very close to that of the classical regulatory agency enables the Member States to oversee the Agency through their presence in the Agency’s central authority, the Management Board. On the other hand, the Member States’ intense involvement in the Article 51 procedure leads to a unique control over the Agency’s decision-making process, resembling that of the Council over the Commission via comitology.

Further improvements were detected with regard to the participation of stakeholders and interested parties in ECHA’s activities. Next to enhanced possibilities for stakeholders to attend Forum and Committee meetings, the Article 51 procedure allows registrants and downstream users to comment on any draft decision before its definite adoption by the Agency or the Commission. Problems were, however, detected with respect to the Agency’s

³¹⁰ Dehousse 2002, loc. cit. n. 4, at p. 17.

judicial accountability. As most complex emerged the legal review of scientific opinions because, similar to EMEA and EFSA, there is no possibility to directly hold the Chemicals Agency accountable for its opinions prepared within the authorisation procedure for substances of very high concern. The answer to the second research question is therefore ambivalent: *on the one side of the coin, considerable improvements could be noted with respect to Member State accountability and social accountability, mainly effected by the Chemicals Agency's novel decision-making process characterised by the Article 51 procedure. On the other side, shortcomings persist with respect to judicial accountability and, particularly, with respect to scientific opinions prepared by the Agency.*

Combining the results of both research questions, one is bound to say that even though the Agency's decision-making powers are not completely reconcilable with the *Meroni* conditions, impairments in the Agency's accountability and control were not recognised. On the contrary, the insertion of the comitology-like control procedure in the decision-making process added considerably to the Chemicals Agency's oversight because Member States as well as stakeholders have been conceded permanent roles therein. Furthermore, the fact that ECHA is able to directly adopt decisions within the substance evaluation procedure does not only avoid time-consuming referrals to the Commission (hence increasing the efficiency of the new chemicals policy), but it also facilitates those decisions' judicial review. Non-transparent and confusing judicial review attempts as those in *Thomae v. Commission* or *Artogodan* can be circumvented.³¹² Yet, what remains problematic, at least until the entering into force of the Lisbon Treaty, is the agencies' absence from the list of reviewable acts under Article 230 EC. To guarantee a proper, standardised review of agencies' decisions, the treaty amendment is inevitable.

The problems identified in the judicial review centre on scientific opinions prepared by ECHA at the authorisation stage. The authorisation process does not follow the Article 51 procedure, but respects the anti-delegation principle; ECHA is, like EMEA and EFSA, not able to adopt its prepared opinions. The result was described as an 'accountability gap' since the actor actually responsible for the contents of the decision hides (or is hidden) behind the administrative machinery of the Commission. Renaud Dehousse comments on this deficiency by saying

³¹¹ Ibid.

³¹² See *Thomae v. Commission*, *supra* n. 111; *Artogodan*, *supra* n. 109.

“[a]re decisions that are made (de facto) by committees and agencies more amenable to judicial [...] control simply because they are formally attributed to the European Commission?” Hardly so.”³¹³

Indeed, if the authorisation decision was to be taken in accordance with the Article 51 procedure, Member States and stakeholders would be more involved in the decision-making procedure than they are at present: it was noted that – surprisingly – the Commission adopts authorisation decisions in accordance with the advisory procedure, meaning that the comitology committee must merely be consulted. In principle, the Commission alone decides on the granting of the authorisation, which is naturally based on highly scientific and technical data. Beyond doubt would the Agency and national experts in the Member State Committee be much more competent to adopt such a decision. Furthermore, the Agency would be directly responsible for the contents of its decision, which could be challenged, first, before the Agency’s internal board of appeal and, second, before the ECJ or the CFI. On the other hand, a decision which is so controversial that not even the Member State Committee can agree on it, is re-transferred to the Commission. Consequently, the Article 51 procedure’s extension to the authorisation of substances of very high concern would further increase the Agency’s accountability and control.

Referring back to the discussion of what the concept of ‘institutional balance’ actually means, the following can be noted: if the concept of institutional balance indeed refers to a system of checks and balances at EU level as suggested above, the fact that the Chemicals Agency can actually be better controlled and held accountable under the Article 51 procedure than under the present authorisation process would mean that the institutional balance is, instead of being disturbed, better preserved under the Article 51 procedure than by the continued adherence to the anti-delegation principle.

Consequently, the Chemicals Agency’s first step away from the outdated conditions of the anti-delegation doctrine has to be seen as a positive development. Its comitology-like decision-making process could function as a blueprint for future regulatory agencies, by illustrating a trade-off between completely independent decision-making powers and none. In any case, the façade erected by the anti-delegation principle has started crumbling.

³¹³ Dehousse 2002, loc. cit. n. 4, at p. 17.

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