

The London School of Economics and Political Science

The Problems and the Controls of the New Administrative State of the EU

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Declaration

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Abstract

Over the last two decades the shape of the European public administration has changed considerably; the EU has become much more strongly involved in the regulation of very dynamic and fluid market activities. One of the consequences of that has been an increasing reliance on EU regulatory agencies to perform the novel administrative tasks. While agencies can be beneficial for the EU, they also generate new problems. In particular, these bodies have limited resources and have to rely on (national and sector) external capacities to a significant extent. There is a risk here that if the important issues are mainly capacity-related and 'liquid', it will be very difficult to ensure 'checks and balances' in these institutional systems. The thesis examines this through case-studies (EU regulatory agencies) in medicines, chemicals, financial services and aviation. It finds that the problems in each EU agency are different and unpredictable. In such a context, having more external and static controls on the agencies will hardly improve things. An alternative 'framework' (that of fluid administrative law) should be considered to deal with the challenges of the new administrative state. It promotes constant administrative law principles (internal process, external justification, commitment to pluralism and policy effectiveness) to coordinate the operation of the agencies, and offers institutional tools for the dynamic application of such principles. As the 'solutions' for each agency should have to vary, the review of these bodies (which usually occurs every three years) could be used to address the required heterogeneity of the controls. In order to make the best use of that exercise, the creation of a new European agency to review the regulatory agencies and make proposals for each of them (according to the fluid law principles) might be envisioned.

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Chapter I

The emergence of the new administrative state of the EU and its challenges

Introduction

Over the last fifteen to twenty years the shape of the European public administration has changed considerably. At least since the bovine spongiform encephalopathy (BSE) crisis, forms of EU social and economic intervention have become more connected with the regulation of complex and sophisticated products and market activities. The European Union has also expanded its reach over fluid and dynamic sectors of the economy, from financial services, energy, transport or telecommunications. The intensity with which the EU now interacts with and regulates these markets emphasises that formal law-making is but one of the ways through which the Union exercises its authority and that new forms of public intervention (involving different actors and including other types of instruments and tools) are becoming more important. The European Union, today, is strongly involved with things such as the assessment and management of 'risks', the approval of (new) products, the daily operation of highly networked sectors or the supervision of financial institutions. The added importance of these tasks stresses the role of the EU 'regulatory expert' and the values of specialised knowledge and expertise which he offers.

One of the effects of these new 'Euro-markets' has been the growing dependence of the Union on regulatory agencies to perform the more dynamic administrative tasks. The proliferation of regulatory agencies in Europe has been rapid since the mid-1990s and new agencies continue to be introduced across a variety of sectors. These agencies have been created because the complexity of the involved market activities makes it too difficult for the problems to be handled by the Commission, or by national regulatory authorities on their own. European regulatory agencies are not really, however, an EU 'equivalent' of their national partners. They include many more actors (the 27 national competent authorities, to start with), tend to focus on particular segments of the regulated markets and have been established to address a series of challenges that are relevant for the EU. While the powers of these agencies vary considerably across sectors, (overall) these bodies take on certain executive responsibilities in their own field of action, provide expert opinions to the Commission and others have decision-making powers in clearly defined cases or operational and inspection related types of work.

The link between a new EU institutional structure (the regulatory agency) and the very dynamic and fluid nature of the new European markets may also create new problems. It puts pressure on the institutional capacity to perform the relevant tasks. EU agencies have, however, (as we shall see below) limited secretariats and internal capabilities. That raises the issue of 'who' they rely on for resources and the risks which that creates. Moreover, the dynamism of these markets would imply that the administrative processes themselves have to become more fluid and adaptable to the own

characteristics and 'motion' of the sectors. It is not clear that we can deal with these issues through more static and external controls on the agencies. These may become more marginal, distant and irrelevant in the context of an administrative power where the problems are of a much more dynamic nature.

This chapter is organised as follows: the first section explores the role of the Commission in the implementation of EU law. It looks at the constraints on this institution with regard to delegation of powers to agencies and examines the structure and evolution of EU comitology processes. Secondly, the chapter considers the emergence of regulatory agencies in the EU. The reasons for having agencies in Europe are then discussed. In the subsequent section, the dynamics of this new administrative state are explored. The final section looks at the mechanics of formal accountability and reflects on the limits of static checks on the agencies.

1- The implementation of EU law and the Commission

Before the European Union decided to create regulatory agencies in many different fields, the executive power of the Union was concentrated on the Commission. That is not to say that the Commission has traditionally had wide-ranging powers of 'direct administration' as the Treaties maintain that the primary responsibility for implementing European Law remains at the national level.¹ Piris explains that this administrative system recognises "the national administrations (tax, customs, veterinary authorities, etc.)" to be the ones with "the necessary infrastructure and resources in terms of manpower and financial and technical means to apply and implement EU law".² In cases, however, where "centralisation has been judged necessary", the Commission was handed direct responsibility to implement EU policies.³ Two important examples of this are the powers of the Commission in competition law (now regulated in Articles 105 and 106 TFEU) and its responsibility for the implementation of the EU budget (Article 317 TFEU).

The Commission also has (as we shall see further below) a series of other powers: legislative and quasi-legislative, agenda-setting and supervisory powers.⁴ There is an issue about the "concentration of so many functions in the Commission" putting much pressure on its resources.⁵ We shall now see that the initial reaction of the Courts in such a context (which dates back to the time of the High Authority and the Coal and Steel Community) was to strongly constrain the conditions under which delegation of powers to other bodies (namely regulatory agencies, whose existence was not 'predicted' by the Treaties) would be allowed to take place.

¹ J. Schwarze, *European Administrative Law*, London, Sweet and Maxwell, 1992, p. 25-27. See also: K. Lenaerts and A. Verhoeven, *Institutional Balance as a Guarantee for Democracy in EU Governance*, in C. Joerges and R. Dehousse (eds.), *Good Governance in Europe's Integrated Market*, Oxford University Press, 2002

² J. C. Piris, *The Lisbon Treaty: A Legal and Political Analysis*, Cambridge University Press, 2010, p. 98

³ *Ibidem*, p. 97-98

⁴ D. Chalmers et al, *European Union Law*, 2nd Edition, Cambridge University Press, 2010, p. 59-64

⁵ *Ibidem*, p. 66

Meroni and the EU regulatory agencies

Since the early days of European integration there has been a question about whether the Commission (and, before that, the High Authority of the ECSC) could delegate powers to other (regulatory) bodies. Once the Court came to examine this issue, in the famous *Meroni vs. High Authority* case, it decided to impose strict conditions for such delegation to take place.⁶

Meroni concerned an “equalisation system” set up to “prevent the prices of ferrous scrap within the Community from being aligned on the higher prices of imported ferrous scrap”.⁷ This system was entrusted to two private law organisations (known as the ‘Brussels agencies’). Between October of 1954 and August of 1956, an office representing the agencies periodically sent to the *Meroni* company a provisional account which showed that it owed the Fund a certain sum.⁸ The central issue in this case was the legality of the delegation of powers to the agencies. The Court assessed whether the decision establishing the financial arrangements for ensuring the regular supply of ferrous scrap in the European market constituted a “true delegation” or whether it only granted those agencies “the power to draw up resolutions the application of which belongs to the High Authority, the latter retaining full responsibility for the same”.⁹ As the High Authority explained that it adopted the “data furnished by the Brussels agencies without being able to add anything thereto”, the Court did not find it too hard to conclude that there had been an effective delegation of competences.¹⁰ Furthermore, the Court was concerned that the powers conferred on the agencies had not been subject to the conditions which would have been used if the High Authority had exercised these tasks directly.¹¹ The Treaty imposed on the High Authority a number of duties (e.g. to state reasons, to publish an annual report and relevant data) that were not transposed to the agencies. According to the applicant, the Brussels accounts were “unassailable and almost sacrosanct and are certainly of greater weight and authority than are decisions proper, which can always be contested before the Court of Justice.”¹² The reply of the Court supported this, but its more general conclusion was beyond procedural:

“The consequences of delegation are very different depending on whether it involves clearly defined executive powers the exercise of which can, therefore, be subject to strict review in the light of objective criteria determined by the delegating authority, or whether it involves a discretionary power, implying wide margin of discretion which may, according to the use which is made of it, make possible the execution of actual economic policy.

⁶ Case 10/56 *Meroni v High Authority*, ECR English special edition Page 00157

⁷ *Ibidem*, p. 159

⁸ *Ibidem*, p. 160

⁹ *Ibidem*, p. 169

¹⁰ *Ibidem*, p. 170

¹¹ *Ibidem*, p. 171

¹² *Ibidem*, p. 168

A delegation of the first kind cannot appreciably alter the consequences involved in the exercise of the powers concerned, whereas a delegation of the second kind, since it replaces the choices of the delegator by the choices of the delegate, brings about an actual transfer of responsibility”.¹³

This was considered to be the case in the institutional environment under which *Meroni* was operating because the agencies were handed a “wide margin of discretion” that involved reconciling a set of difficult and complex economic policy considerations.¹⁴ For the Court, this was inconsistent with Article 3 of the Treaty, where it was said that the objectives of the Community were binding on its institutions “within the limits of their respective powers, in the common interest.”¹⁵ This provision established a system of “balance of powers”, the distinctiveness of which constitutes a fundamental “guarantee granted by the Treaty in particular to the undertakings and associations of undertakings to which it applies”.¹⁶

Meroni has been the subject of much criticism and controversy.¹⁷ There are also legitimate questions about whether some of the agencies which the EU has created in more recent times (see below) would be considered by the Court to be compatible with the Treaties if (or when) it looks into the matter.¹⁸ In any case, it is worth distinguishing between two parts of the *Meroni* ruling. The first, which is often overlooked, is that the Union (then Community...) cannot use a delegation of powers to place the regulated parties in a position which is worse than the one in which they would find themselves if this transfer of tasks had not occurred in the first place. That would suggest that as long as the Union is able to subject the exercise of delegated powers to conditions similar to those which apply to the Commission (e.g. duty to give reasons, other procedural guarantees) no legal problems would arise. The second point in *Meroni* is that the system of “balance of powers” enshrined in the Treaties represents an important guarantee to those affected by European public power. While the first point could suggest the existence of a problem linked to the particular circumstances of *Meroni* (lack of legal safeguards and controls in the agencies); the balance of powers argument indicates that there are wider issues of accountability (and about the reshaping of the institutional settlement) which have to be taken into account. What *Meroni* ends up doing (and here lies perhaps its major weakness) is to

¹³ *Ibidem*, p. 173

¹⁴ *Ibidem*, p. 174

¹⁵ *Ibidem*, p. 173

¹⁶ *Ibidem*

¹⁷ See: G. Majone, *The Credibility Crisis of Community Regulation*, Journal of Common Market Studies, Vol. 38, No 2, 2000, pp. 273-302. For another article which pays attention to the *Meroni* ruling, see: M. Everson, *Independent Agencies: Hierarchy Beaters?*, European Law Journal, Vol. 1, No. 2, 1995, pp. 180-204

¹⁸ The Court continues to cite *Meroni* in its case-law. Cases where the Court has referred to *Meroni* include: Case C-255/04 *Commission v France*, ECR 2006 Page I-05251; Case C-240/03 P. *Comunità montana della Valnerina v Commission*, ECR 2006 Page I-00731; Case C-301/02 P. *Carmine Salvatore Tralli v European Central Bank*, ECR 2005 Page I-4071. There have also been cases where the Court appears to hold on to the basic rationale of *Meroni* without nevertheless referring to it explicitly. This happened in *Romano*: Case 98/80 *Giuseppe Romano v Institut national d'assurance maladie-invalidité*, ECR 1981 Page 01241. For an analysis of *Romano*, see: M. Chamon, *EU Agencies between Meroni and Romano or the devil and the deep blue sea*, Common Market Law Review, Vol. 48, No. 4, 2011, pp. 1055-1075

emphasise the *ex ante* division of tasks between the Commission and the agencies, when attention might instead be focused on the controls on the latter.

The structure and evolution of EU comitology

The readiness of the Court to put a brake to delegations of power from the Commission to EU regulatory agencies contrasts with its readiness to accept (since the early days of the European project) substantial transfers of law-making responsibilities from the Council to the Commission. As Bergström explains, an “early expression of [that transfer] can be found in a ruling from 1970 [Köster] where the Court manifested its support for the idea that the Council should delegate ‘a general implementing power’ to the Commission.”¹⁹ Köster concerned the legality of a ‘management committee’ set up by the Council to control the exercise of certain implementing powers handed to the Commission in the field of agricultural policy.²⁰ For the Court, the Treaty established a distinction between “the measures directly based on the Treaty itself and the derived law intended to ensure their implementation” and it could not be expected that “all the details of the regulations concerning common agricultural policy be drawn up by the Council” according to the traditional law-making processes of the Community.²¹ The Council only has to adopt the “basic elements” of the matter at hand and the remaining issues may then be dealt with by the Commission, following a Council “authorisation”.²² Moreover, the Council was allowed to determine the conditions under which the implementing powers of the Commission would be exercised: the so-called management committee procedure [which integrated representatives of the national administrations] forms part of the detailed rules to which the Council may legitimately subject a delegation of power to the Commission”.²³ The management committee was created to “give opinions on draft measures proposed by the Commission”, and the constraint on the Commission was only that in case the opinion of the committee was negative, the measures taken would have to be communicated to the Council.²⁴ The Court concluded that “without distorting community structure and the institutional balance” the management committee system allowed the Council “to delegate to the Commission an implementing power of appreciable scope, subject to its power to take the decision itself if necessary.”²⁵

¹⁹ C. F. Bergström, *Comitology: Delegation of Powers in the European Union and the Committee System*, Oxford University Press, 2005, p. 2

²⁰ Case 25/70 *Einfuhr- und Vorratsstelle für Getreide und Futtermittel v Köster et Berodt & Co.*, ECR 1970 Page 01161. This case is often cited in the Court’s judgements. See, for example: Case 230/78 *SpA Eridania-Zuccherifici nazionali and others v Minister of Agriculture and Forestry*, ECR 1979 Page 02749; Joined cases T-64/01 and T-65/01 *Afrikanische Frucht-Compagnie GmbH and others v Council*, ECR 2004 Page II-00521

²¹ *Ibidem* [Köster], Paragraph 6

²² *Ibidem*

²³ *Ibidem*, Paragraph 9

²⁴ *Ibidem*

²⁵ *Ibidem*

The easiness of the Court in Köster regarding the delegation of law-making responsibilities from the Council to the Commission sits rather uneasily with the problems which the Court had in Meroni about allowing some highly specialised tasks to be performed by new EU technical bodies working under the supervision of the Commission. To be sure, “highly significant matters have been delegated” to the Commission through the committee system and there are important questions about the “democratic accountability” of the whole process and the “modest controls” which it places on the Commission.²⁶ Before the Lisbon Treaty changes on comitology (which are considered below), the way in which the national checks on the Commission’s exercise of implementing powers worked according to a set of different procedures which were set out in Decision 1999/468/EC.²⁷ Comitology has included four main procedures: the advisory procedure, the management procedure, the regulatory procedure and the regulatory procedure with scrutiny.²⁸ In the advisory procedure, the committee “delivers a purely consultative opinion” of the draft Commission measures, and the Commission then has to “take the utmost account” of the opinion’.²⁹ In all the other procedures, the committee “has a fire-warning role”: it has “to decide whether or not the Commission draft should be referred to the Council.”³⁰ Under the management procedure, if the committee does not agree with the draft Commission measures it can refer them to the Council by QMV.³¹ A major concern with this particular procedure has been that even if the majority of the national representatives disagreed with the Commission, it was still possible for the latter to adopt the measures.³² A similar situation was not possible under the regulatory procedure, where the committee has to “positively agree to the Commission draft by QMV” and if that failed to happen, the matter would then get referred to the Council (which has three months to adopt its decision).³³ Chalmers explains that the “regulatory procedure contains its own perversity, which is the difference between the voting thresholds in the committee and those in the Council”: a QMV “must actively *support*” the draft Commission measures in order for them not be sent to the Council, whereas the latter needs a QMV majority to actively *oppose* the measure or support an alternative for the Commission draft not to become draft.”³⁴ Accordingly, there is “space for the Commission to adopt measures unchecked.”³⁵

Comitology has been the source of much institutional tension due to the role of the Parliament in the supervision of the Commission and of the workings of the committee system more generally. In the context of the regulatory procedure, the Parliament only had to be informed if the committee failed to support the draft Commission measures and could then submit an opinion to the Council where it

²⁶ Supra 4, [Chalmers et al, 2010], p. 60

²⁷ Council Decision 1999/468/EC, OJ L 184, 17.7.1999, p. 23–26

²⁸ Supra 4, [Chalmers 2010], p. 117-122

²⁹ Supra 2, [Piris, Lisbon Treaty], p. 101

³⁰ Supra 4, [Chalmers et al, 2010], p. 118

³¹ *Ibidem*

³² *Ibidem*, p. 118 and 119

³³ *Ibidem*, p. 119

³⁴ *Ibidem*

³⁵ *Ibidem*

considered that those measures exceeded the implementing powers granted to the Commission by the basic legislative act.³⁶ The Parliament became “increasingly uneasy during the 1990s about delegating powers to the Commission that it thought would be better exercised by the ordinary legislative procedure (then co-decision procedure).³⁷ It was then agreed “that regulatory measures based on a parent instrument adopted under the ordinary legislative procedure would be notified to the Parliament and it could object through a Resolution if it considered they exceeded the implementing power granted by the parent instrument”; and (under Article 8 of Decision 1999/688/EC) the Commission vowed to take into account the opinion of the Parliament and reconsider the relevant measures.³⁸ This system did not work well. The Commission did not have to give up the measures but only provide reasons to the Parliament on its decision; and it later admitted that it continued to often disregard parliamentary prerogatives in comitology.³⁹ These difficulties led to the creation of the ‘regulatory procedure with scrutiny’ (PRAC), which applies only to measures considered to ‘amend’ the basic law-making instrument in cases where the latter was approved via the ordinary legislative procedure.⁴⁰ Under this procedure, if the committee delivers a positive opinion, “the Commission has to submit the draft measures for scrutiny by the European Parliament and the Council” and either of the institutions may (within three months) decide to oppose the draft measures in case they “‘exceed the implementing powers provided for in the basic instrument’ or if the draft is incompatible ‘with the aim of or the content of the basic instrument or does not respect the principles of subsidiarity or proportionality’.”⁴¹ In that case, the Commission may “submit to the Committee an amended draft of the measures” or present a new legislative proposal.⁴² Otherwise, the measures may be adopted. If, on the other hand, the committee disagrees with the draft, “the same possibilities exist except that this time the Council can decide to oppose the measure *for any reason* and this pre-empts any consideration by the Parliament, which only looks at the draft if the Council is inclined to accept it.”⁴³ In case the “Council envisages adopting the measures, the European Parliament is to be seized with a maximum of two months for scrutiny of the draft measures” and may oppose them for similar reasons.⁴⁴ We shall see later on in the chapter that it is the Council which has benefited from this procedure, not really the Parliament.⁴⁵ These lessons may be useful when considering the increasing calls for (more) parliamentary controls on EU regulatory agencies (see below).

The control of delegated powers of the Commission has been changed with the entry into force of the Lisbon Treaty. The new regime makes a distinction between delegated acts (Article 290 TFEU) and

³⁶ Supra 27, [Council Decision 1999/468/EC], Article 5 (4)-(5)

³⁷ Supra 4, [Chalmers et al, 2010], p. 120

³⁸ *Ibidem*

³⁹ *Ibidem*

⁴⁰ Council Decision 2006/512/EC, *OJ L 200*, 22.7.2006, p. 11–13

⁴¹ Supra 2, [Piris, Lisbon Treaty], p. 101

⁴² *Ibidem*

⁴³ Supra 4, [Chalmers et al, 2010], p. 120

⁴⁴ Supra 2, [Piris, Lisbon Treaty], p. 101-102

⁴⁵ Supra 4, [Chalmers et al, 2010], p. 120-121

implementing acts (Article 291 TFEU). With respect to the *delegated* acts, the control of the Commission falls exclusively on the Council and the Parliament.⁴⁶ On the other hand, with regard to *implementing* acts, the controls on the Commission are performed by the Member States. The new procedures for Member State control of the Commission's implementing powers are now established in an EU Regulation.⁴⁷ The regime suggests that delegated acts constitute the standard way of handing power to the Commission in the definition of the technical rules, whereas the implementing acts essentially involve 'filling in' the gaps.

Article 290 (TFEU)

1. A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act. [...]
2. Legislative acts shall explicitly lay down the conditions to which the delegation is subject; these conditions may be as follows:
 - (a) the European Parliament or the Council may decide to revoke the delegation;
 - (b) the delegated act may enter into force only if no objection has been expressed by the European Parliament or the Council within a period set by the legislative act.

Article 291 (TFEU)

- (2) Where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission...
- (3) ...the European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall lay down in advance the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

The distinction between delegated and implementing acts is a fluid one. Institutionally, it may be read in the context of the power which, over the years, the Parliament has acquired in comitology and (particularly) taking into account the creation, in 2006, of the PRAC (regulatory procedure with scrutiny).⁴⁸ As Piris explains, with the entry into force of the Lisbon Treaty, the PRAC "is no longer needed as Article 290 TFEU provides for the procedure to be followed in such cases."⁴⁹ The Lisbon Treaty consolidates the controls of the Parliament and of the Council vis-à-vis the Commission with respect to a particular type of [delegated] act (i.e. acts of general application which seek to amend or supplement certain non-essential elements of the basic legislative instrument) but then eliminates those institutional checks in areas which are considered to be of an 'implementing' nature.⁵⁰

⁴⁶ *Ibidem*, p. 121

⁴⁷ Regulation (EU) No 182/2011 of the European Parliament and the Council, *OJ L55/13 28.2.2011*, p. 13-18

⁴⁸ See: H. Hofmann, *Legislation, Delegation and Implementation under the Treaty of Lisbon: Typology Meets Reality*, *European Law Journal*, Vol. 15, No. 4, 2009, p. 496

⁴⁹ *Supra* 2, [Piris, Lisbon Treaty], p. 103. Piris also notes (in the same page) that: "All legislative acts adopted in the past and which contain PRAC procedures will remain applicable until they are modified."

⁵⁰ Article 290(1) TFEU. See also: European Commission, Communication to the European Parliament and the Council: Implementation of Article 290 of the Treaty on the Functioning of the European Union, Brussels, 9.12.2009, COM(2009) 673 final, p. 4

With respect to the 'delegated powers' regime, the Parliament and the Council have at their disposal two main instruments to control the Commission at this level: the right of opposition and revocation.⁵¹ To exercise any of the prerogatives, the Parliament should "act by a majority of its component members, and the Council by a qualified majority."⁵² While the power to express objections is clearly directed at a particular delegated act, the revocation is a "general and absolute withdrawal of the delegated powers from the Commission."⁵³ The Commission considers that "opposition should thus be seen as the ordinary means of control exercised by the legislator over all delegated acts" and that "revocation appears to be a more exceptional measure, prompted for example by the occurrence of factors that undermine the very basis of the delegation of power."⁵⁴ Revocation may also be used where the exercise of the expression of objections "would be ineffective or impractical", namely because the Commission has to adopt the delegated acts "subject to time constraints that are incompatible with the exercise of a right of opposition by the legislator."⁵⁵ According to the Commission, the exercise of the right of revocation by the institutions should also be accompanied by a duty to give reasons (where provided for in the legislative act).⁵⁶ This allows the other institution which was not exercising the right of revocation to better understand the motivations behind that initiative while clearly informing the Commission on what 'went wrong'.⁵⁷ There is also an issue about 'partial revocation'. The Commission considers that the institution initiating the revocation should "explicitly state which delegated powers it is seeking to revoke" and it should be possible for the Parliament or the Council "to revoke only some of the powers delegated to the Commission."⁵⁸ Finally, it is also considered by the Commission that the revocation of the delegated powers does not necessarily affect the delegated acts which are already in force (the exact consequences should hence be set out in the basic legislative instrument).⁵⁹ In conclusion, the ability of the EU legislator to revoke the delegated act is important and new. Before the Lisbon Treaty, a similar objective could only be achieved through a new legislative procedure, which of course required a proposal from the Commission.⁶⁰ The Commission will therefore be exercising its (delegated) powers "under the shadow of the sword with the possibility that if does something institutionally unpopular it will suffer the consequences."⁶¹

Differently, the control of the implementing powers of the Commission falls on the Member States (Article 291 TFEU). The power to adopt the implementing acts is conferred on the Commission (or on the Council, in "duly justified" cases or in CFSP and ESDP matters) "where uniform conditions for

⁵¹ Article 290(2) - 'a' and 'b' TFEU

⁵² Article 290(2) TFEU

⁵³ Supra 50, [COM Communication on Article 290 TFEU], p. 7

⁵⁴ *Ibidem*

⁵⁵ *Ibidem*, p. 8

⁵⁶ *Ibidem*

⁵⁷ *Ibidem*

⁵⁸ *Ibidem*

⁵⁹ *Ibidem*

⁶⁰ *Ibidem*

⁶¹ Supra 4, [Chalmers et al, 2010], p.121

implementing binding acts are needed”.⁶² Regulation (EU) 182/2011 distinguishes between two different (committee) procedures for the control of the Commission by the Member States: the ‘advisory’ and the ‘examination’ procedure.⁶³ The examination procedure applies (in particular) for the adoption of: a) implementing acts of general scope; b) other implementing acts relating to (i) programmes with substantial implications; (ii) the common agricultural and common fisheries policies, (iii) the environment, security and safety, or protection of the health or safety, of humans, animals or plants; (iv) the common commercial policy; and (v) taxation.⁶⁴ The advisory procedure, on the other hand, applies (as a general rule) for the adoption of acts which are not directly associated to the examination procedure (although in ‘duly justified cases’ it can also apply to those acts).⁶⁵ Under the advisory procedure, the committee delivers its opinion by simple majority and the Commission then has to take the “utmost account” of it.⁶⁶

The power of the new (examination) committee lies essentially in that there is no possibility of reference to the Council. In case the committee gives a negative opinion (by QMV), the Commission cannot adopt the measures.⁶⁷ This rule may be overturned in exceptional cases where the implementing act “needs to be adopted without delay in order to avoid creating a significant disruption of the markets in the area of agriculture or a risk for the financial interests of the Union [...]”.⁶⁸ If, on the other hand, the examination committee does not deliver an opinion the Commission may adopt the implementing act (subject to a series of exceptions).⁶⁹ Consequently, even if the committee has not rejected the draft implementing act the Commission is prevented from adopting it where: a) that act concerns taxation, financial services, the protection of the health or safety of humans, animals or plants, or definitive multilateral safeguard measures; b) the basic act provides that the draft implementing act may not be adopted where no opinion is delivered; or c) a simple majority of the component members of the committee opposes it.⁷⁰ The fact that the Commission is *a priori* stopped from adopting the draft implementing act in certain policy areas, even if the majority of the members of the committee members are not against it, is odd and very restrictive.⁷¹

⁶² Supra 2, [Piris, Lisbon Treaty], p. 103

⁶³ Supra 47, [Comitology Regulation 2011]

⁶⁴ *Ibidem*, Article 2 (2)

⁶⁵ *Ibidem*, Article 2(3)

⁶⁶ *Ibidem*, Article 4 (1) and (2)

⁶⁷ *Ibidem*, Article 5(3)

⁶⁸ *Ibidem*, Article 7. In such cases the Commission has (according to the same article) to “immediately submit the adopted implementing act to the appeal committee.” If the appeal committee then issues a negative opinion on the adopted implementing act, the Commission has to repeal that act right away (otherwise the act remains in place)

⁶⁹ *Ibidem*, Article 5(4)

⁷⁰ *Ibidem*, Article 4 (a) (b) and (c)

⁷¹ Article 5(5) of the new Comitology Regulation also indicates that a different procedure shall apply “for the adoption of draft definitive anti-dumping or countervailing measures, where no opinion is delivered by the committee and a simple majority of its component members opposes the draft implementing act.”

On the other hand, the Commission can also increase the pressure on the committee to approve the draft implementing act. The role of the 'appeal committee' is particularly important in this regard.⁷² The appeal committee represents a sort of 'second round' deliberation, where the national administrations are asked to reconsider either their opposition to (or lack of support for) the Commission measures.⁷³ In either of those scenarios and where "an implementing act is deemed to be necessary", the chair of the examination committee can either submit an amended version of the draft implementing act to the same committee within 2 months or submit the draft implementing act within 1 month to the appeal committee "for further deliberation".⁷⁴ The national controls on the Commission are laxer in the appeal committee. As long as the latter does not deliver a negative opinion, the Commission may adopt the implementing act (this does not apply for the adoption of definitive multilateral safeguard measures, where the Commission cannot adopt the draft act without the active support of the appeal committee).⁷⁵ In case the draft implementing acts concern "particularly sensitive sectors, notably taxation, consumer health, food safety and protection of the environment", the Commission nevertheless has to "avoid going against any predominant position" within the appeal committee against the appropriateness of an implementing act.⁷⁶

Finally, while the Council and the Parliament are excluded (under Article 291 TFEU) from the control of the implementing powers of the Commission, the Comitology Regulation provides them with a "right of scrutiny".⁷⁷ This essentially means that where the basic act has been approved under the ordinary legislative procedure, either the Council or the Parliament may indicate to the Commission that, in their view, the draft implementing act goes beyond the implementing powers provided for in the basic act.⁷⁸ Where such concerns have been expressed, the Commission has to review the draft implement act and take into account those positions, but it remains free to maintain the draft implementing act if it so wishes.⁷⁹

2- The emergence of a new administrative model: the 'four waves' of European agencies

The comitology system has evolved, as noted above, hand in hand with the emergence of new administrative structures in Europe. In 1975 the first European agencies were introduced with the establishment of the European Centre for the Development of Vocational Training (Cedefop)⁸⁰ and the European Foundation for the Improvement of Living and Working conditions (EUROFUND).⁸¹

⁷² Supra 47, [Comitology Regulation 2011], Article 6

⁷³ *Ibidem*, Article 5(3) and (4)

⁷⁴ *Ibidem*, Article 5(3)

⁷⁵ *Ibidem*, Article 6(3) and (4)

⁷⁶ *Ibidem*, Recital (14)

⁷⁷ *Ibidem*, Article 11

⁷⁸ *Ibidem*

⁷⁹ *Ibidem*

⁸⁰ Council Regulation (EEC) No. 337/75, *OL L39*, 13.2.1975, p. 1–4

⁸¹ Council Regulation (EEC) No. 1365/75, *OJ L 139*, 30.5.1975, p. 1–4

These two bodies were mainly created for information collection purposes. This is visible in the mission of Cedefop, which compiles documentation and analyses of data, develops research and offers a debating forum on vocational training issues. The first EU agencies were therefore handed very confined powers and the idea behind them was mainly that the Commission could outsource particularly time-consuming and specialised tasks, allowing it to focus on its core functions of policy initiation and implementation.⁸²

The reliance on 'regulatory' agencies acquired new momentum during the 1990s, in the context of the completion of the internal market. Some of these agencies also highlighted the Union's increasing reach over matters of social relevance such as gender equality, racism or drug addiction issues. In total, during that decade eleven agencies were introduced: the European Environmental Agency (EEA)⁸³; the European Training Foundation (ETF)⁸⁴, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)⁸⁵; the European Medicines Agency (EMA)⁸⁶; the Office for Harmonisation of the Internal Market (OHIM)⁸⁷; the European Agency for Health and Safety at work (EU-OSHA)⁸⁸; the Community Plant Variety Office (CPVO)⁸⁹; the European Institute for Gender Equality (EIGE)⁹⁰; the Translation Centre for Bodies of the European Union (CdT)⁹¹; the European Monitoring Centre for Racism and Xenophobia (EUMC)⁹²; and the European Agency for Reconstruction (EAR)⁹³. With two exceptions (the EMA, for medicines; and the OHIM, for trademarks), all of these bodies' were created for the collection and analysis of information. One of the authorities which stands out is the Office for the Harmonisation of the Internal Market, which can adopt decisions binding on third parties regarding trademarks and designs registrations. The OHIM introduces a new layer of (EU) industrial property rights so that companies might rely on them when operating across borders. The European Medicines Agency, on the other hand, has been entrusted with risk assessment and advice functions. Its scientific opinions on medicinal products are relied on by the Commission, which authorises them. The EMA is not responsible for the scientific evaluation of all medicines in Europe. Its central responsibility is the assessment of particularly innovative medicines (namely those derived from biotechnological processes) through the so called 'centralised procedure'. The EMA hence opened up a new layer of product approvals, which was mandatory for the biotech products. The reason for this was tied to the problems with the decentralised systems of medicines authorisation in Europe (i.e. mutual recognition), which were not working well due to lack of trust between the national authorities.

⁸² Supra 4, [Chalmers et al, 2010], p. 66

⁸³ Regulation (EC) No. 401/2009 of the European Parliament and of the Council, *OJ L 126*, 21.5.2009, p. 13–22

⁸⁴ Council Regulation (EEC) No. 1360/90, *OJ L 131*, 23.5.1990, p. 1–5

⁸⁵ Council Regulation (EEC) No 302/93, *OJ L 36*, 12.2.1993, p. 1–8

⁸⁶ Regulation (EC) No. 726/2004 of the European Parliament and of the Council, *OJ L 136*, 30.4.2004, p. 1–33

⁸⁷ Council Regulation (EC) No. 207/2009, *OJ L 78*, 24.3.2009, p. 1–42

⁸⁸ Council Regulation (EC) No. 2062/94, *OJ L 216*, 20.8.1994, p. 1–8

⁸⁹ Council Regulation (EC) No. 2100/94, *OJ L 227*, 1.9.1994, p. 1–30

⁹⁰ Regulation (EC) No. 1922/2006 of the European Parliament and of the Council, *OJ L 403*, 30.12.2006, p. 9–17

⁹¹ Council Regulation (EC) No. 2965/94, *OL L314*, 7.12.1994

⁹² Council Regulation (EC) No. 1035/97, *OJ L151*, 10.6.1997

⁹³ Council Regulation (EC) 1628/1996, *OJ L 204*, 14.8.1996, p. 1–5

The BSE crisis and the new law of socio-economic regulation

The status of regulatory systems in Europe changed significantly after the Commission, and the Union more generally, got mixed up in two major crises during the late 1990s. The outbreak of the bovine spongiform encephalopathy (BSE) scandal highlighted a set of serious problems in the handling of the 'knowledge' on this issue by the Commission.⁹⁴ Post-crisis evaluations portrayed this institution as being too influenced by "British thinking" as a consequence of the "number of British officials sitting in two relevant committees: the Scientific Veterinary Committee and the Standing Veterinary Committee".⁹⁵ The independence and competence of the Commission, (as a regulator) was seriously brought into question; while the reliability and transparency of comitology also began to be contested. On top of this, the mismanagement cases which ultimately led to the fall of the Santer Commission handed another huge blow to the credibility and prestige of the Commission.⁹⁶ This period has therefore become badly associated with an un-transparent and problematic entanglement between politics and science, by a dominance of *ad hoc* approaches to the handling of risk and allegations of undue influences in areas where citizens' trust in the public powers is important.

Following these difficulties, one of the central indications of the Task Force on Administrative Reform (1999) was that the Commission should do less administration and delegate more tasks to agencies.⁹⁷ This idea was then appropriated by the Commission in its White Paper on Governance (2001), which proposed to accelerate the introduction of further European regulatory agencies in areas where a single public interest dominates:

The creation of further autonomous **EU regulatory agencies** in clearly defined areas will improve the way rules are applied and enforced across the Union. Such agencies should be granted the power to take individual decisions in application of regulatory measures. They should operate with a degree of independence and within a clear framework established by the legislature. The regulation creating each agency should set out the limits of their activities and powers, their responsibilities and requirements for openness.⁹⁸ [Emphasis original]

The Commission then sets out the expected benefits:

The advantage of agencies is often their ability to draw on highly technical, sectoral know-how, the increased visibility they give for the sectors concerned (and sometimes the public) and the cost-savings that they offer to business. For the Commission, the creation of agencies is also a useful way of ensuring it focuses resources on core tasks.⁹⁹

⁹⁴ Supra 4, [Chalmers et al, 2010], p. 66

⁹⁵ E. Vos, *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, Journal of Consumer Policy, Vol. 23, No. 3, 2000, p. 228

⁹⁶ See: R. Dehousse, *Misfits: EU Law and the Transformation of European Governance*, Jean Monnet Working Paper 2/02 Available at: <http://centers.law.nyu.edu/jeanmonnet/papers/02/020201.html>

⁹⁷ European Commission – 'Reforming the Commission', COM(2000) 200, Part I, 6

⁹⁸ European Commission – 'European Governance: A White Paper', Brussels, 25.7.2001, COM(2001) 428 final, p. 24

⁹⁹ *Ibidem*

Since 2004 a number of additional agencies have been created: the European Food Safety Authority (EFSA)¹⁰⁰; the European Maritime Safety Agency (EMSA)¹⁰¹; the European Aviation Safety Agency (EASA)¹⁰²; the European Network and Information Security Agency (ENISA)¹⁰³; the European Centre for Disease and Prevention and Control (ECDC)¹⁰⁴; the European Railways Agency (ERA)¹⁰⁵; the Community Fisheries Control Agency (CFCA)¹⁰⁶; the European Chemicals Agency (ECHA)¹⁰⁷; the European Fundamental Rights Agency (FRA)¹⁰⁸; the European Agency for the Management of Operation Cooperation at the External Borders of the Member States (FRONTEX)¹⁰⁹ or the European Global Navigation Satellite Systems Supervisors Authority (GSA).¹¹⁰ While their functions may vary considerably, the “most wide-ranging power granted to a number of agencies is to provide expert opinion, which will either guide other EU institutions in deciding whether to authorise a product or activity or inform legislation they wish to develop in this field.”¹¹¹ Whereas EU institutions are not obliged to follow with these ‘opinions’ for the adoption of legislation or granting of product authorisations, “there is invariably a duty to consult the agency” before departing from the latter’s advice.¹¹² Moreover, the EU institutions “can then depart from the agency’s Opinion only on grounds of safety where it can provide an alternative, equally authoritative, contradictory opinion.”¹¹³ The effect of this has been that, for example, the EFSA “has become the central institution for determining which food may be marketed in the European Union.”¹¹⁴ This then “allows both the acquisition of new EU capacities and the taking of important decisions behind the cloak of ‘expertise’”.¹¹⁵ For Azoulay, the “core of the new stage is the ‘mad cow crisis’, with the need to invent a new ‘law of economic and social regulation’ and the project of creating the conditions for a ‘good governance’ in Europe”.¹¹⁶

Be it as it may, this has not been the end of the line for comitology. On the contrary, the committee system keeps growing in the EU: a total of 270 committees were in operation by the end of 2008.¹¹⁷ Defending this governance model, Joerges has observed that the “much maligned comitology has the

¹⁰⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council, *OJ L 31*, 1.2.2002, p. 1–24

¹⁰¹ Regulation (EC) No 1406/2002 of the European Parliament and of the Council, *OJ L 208*, 5.8.2002, p. 1–9

¹⁰² Council Regulation (EC) No. 1592/2002 of the European Parliament and of the Council, *OJ L 240*, 7.9.2002, p. 1–21

¹⁰³ Regulation (EC) No 460/2004 of the European Parliament and of the Council, *OJ L 77*, 13.3.2004, p. 1–11

¹⁰⁴ Regulation (EC) No 851/2004 of the European Parliament and of the Council, *OJ L 142*, 30.4.2004, p. 1–11

¹⁰⁵ Regulation (EC) No 881/2004 of the European Parliament and of the Council, *OJ L 164*, 30.4.2004, p. 1–43. Amended by: Regulation (EC) No 1335/2008 of the European Parliament and of the Council, *OJ L 354*, 31.12.2008, p. 51–59

¹⁰⁶ Council Regulation (EC) No. 768/2005, *OJ L 128*, 21.5.2005, p. 1–14

¹⁰⁷ Regulation (EC) No 1907/2006 of the European Parliament and of the Council, *OJ L 396*, 30.12.2006, p. 1–849

¹⁰⁸ Council Regulation (EC) No 168/2007, *OJ L 53*, 22.2.2007, p. 1–14

¹⁰⁹ Council Regulation (EC) No 2007/2004, *OJ L 349/25*, 25.11.2004

¹¹⁰ Council Regulation (EC) No 1321/2004, *OJ L 246*, 20.7.2004, p. 1–9

¹¹¹ Supra 4, [Chalmers et al, 2010], p. 66

¹¹² *Ibidem*

¹¹³ *Ibidem*; see: Case T-13/99 *Pfizer animal Health vs. Council* [2002] ECR II – 3305, p. 380-2

¹¹⁴ *Ibidem*

¹¹⁵ *Ibidem*

¹¹⁶ L. Azoulay, *The Court of Justice and the Administrative Governance*, *European Law Journal*, Vol. 7, No. 4, 2001, p. 428

¹¹⁷ Supra 4, [Chalmers et al, 2010], p. 117

advantage over agencies of the American pattern in that it structures risk policy pluralistically, that national bureaucracies have to face up to the positions of their neighbour states, and that interests and concerns in Member States cannot be filtered out.”¹¹⁸ But we also know from experience that the mix between EU politics and technocracy has its risks and, in any case, it is ill-suited to deal with more complex and dynamic market activities where a more intimate involvement with the sector is needed and specialised expertise becomes more important. Moreover, the Commission has also become more dependent on regulatory networks for the implementation of EU law. Even in the field of EU competition, where the Treaties charge the Commission with the direct execution of the policy, this institution has had to decentralise the enforcement of those rules through the creation of a European Competition Network, integrating the National Competent Authorities.¹¹⁹

(i) Executive agencies. In recent years the Union has also created six ‘executive agencies’: the Education, Audiovisual and Culture Executive Agency (EACEA); the European Research Council Executive Agency (ERC); the European Agency for Competitiveness and Innovation (EACI), the Executive Agency for Health and Consumers (EAHC); the Research Executive Agency (REA), and the Trans-European Transport Executive Agency (TEN-T EA). The institutional position of the executive agencies is less problematic as they are not independent and operate under full responsibility of the Commission. These executive bodies have all been created in accordance with a Council Regulation (2002), assigning the former to the management of specific EU programmes.¹²⁰ Their lifetime is therefore limited while headquarters remain closely located to the Commission. With the introduction of executive agencies the Commission outsources certain management related tasks of the Community programmes and, more specifically, the financial and accounting work which needs to be performed in relation to them.

(ii) CSDP and PJCC agencies. EU agencies have also been introduced in the areas of security and defence, as well as in police and judicial cooperation issues. Concerning common security and defence, three bodies have been established: the European Defence Agency (EDA)¹²¹; the European Union Institute for Security Studies (ISS)¹²²; and the European Union Satellite Centre (EUCS).¹²³ Their powers are limited; mostly confined to the preparation of analyses and issuing of policy recommendations. Regarding police and judicial cooperation in criminal matters, three agencies are currently in operation: the European Police College (CEPOL)¹²⁴; the European Police Office

¹¹⁸ C. Joerges, *Deliberative Supranationalism: A Defence*, European Integration Online Papers (EIoP), Vol. 5, No 8, 2001, p. 8-9

¹¹⁹ Council Regulation (EC) No 1/2003, *OJ L 1*, 4.1.2003, p. 1–25

¹²⁰ Council Regulation (EC) No 58/2003, *OL L11/1* 16.1.2003

¹²¹ Council Joint Action 2004/551/CFSP, *OJ L 245*, 17.7.2004, p. 17–28

¹²² Council Joint Action 2001/554/CFSP, *OJ L 200/1*, 25.7.2001, revised by: Council Joint Action 2006/1002/CFSP, *OJ L 409*, 30.12.2006, p. 181–188

¹²³ Council Joint Action 2001/555/CFSP, *OJ L 200/5*, 25.7.2001

¹²⁴ Council Decision 2005/681/JHA, *OJ L 256*, 1.10.2005, p. 63–70

(EUROPOL)¹²⁵; and the European Union's Judicial Cooperation Unit (EUROJUST).¹²⁶ The most significant of these bodies is EUROPOL, the law enforcement agency of the EU. It was set up in 1992 to coordinate national police authorities by collecting, analysing and disseminating information and coordinating operations. The Europol experts and analysts can also integrate joint investigation teams dealing with criminal cases on the spot, but the power of arrest remains with the national police of the concerned Member State(s).

The emergence of a new breed of EU regulatory systems

Before the European Union established agencies (or authorities) in the field of financial services, this area had been 'governed' by decentralised regulatory structures known as the 'Lamfalussy' committees.¹²⁷ Three Lamfalussy committees were created in 2001: the European Securities Regulators (CESR)¹²⁸, the Committee of European Banking Supervisors (CEBS)¹²⁹ and the Committee of European Insurance and Occupational Pensions Committee (CEIOPS).¹³⁰ They were established to issue non-mandatory guidelines for the implementation of EU financial services legislation. Following the 2008 financial troubles, it was decided to transform these structures into formal EU agencies and to grant them powers to issue binding technical guidelines. The new bodies are: the European Securities and Markets Authority (ESMA)¹³¹, the European Banking Authority (EBA)¹³², and the European Insurance and Occupational Pensions Authority (EIOPA).¹³³ The new architecture of EU financial services supervision also includes a European Systemic Risk Board (ESRB), to deal with macro-prudential supervision matters.¹³⁴ The ESRB is not a regulatory agency and its links are clearly directed towards the European Central Bank. With the introduction of this Board the EU hopes to be able to monitor and assess systemic financial risk so as to avoid future crises. Together with the three micro-supervisory bodies (ESMA, EBA and EIOPA) the ESRB integrates a European System of Financial Supervision (ESFS) "bringing together the actors of financial supervision at national level and at the level of the Union, to act as a network."¹³⁵

In energy and electronic communications, new bodies have also been established: respectively, the Agency for the Cooperation of Energy Regulators (ACER)¹³⁶ and the Body of European Regulators for

¹²⁵ Council Decision 2009/371/JHA, *OJ L 121*, 15.5.2009, p. 37–66

¹²⁶ Council Decision 2002/187/JHA, *OJ L 63*, 6.3.2002, p. 1–13

¹²⁷ Final Report of the Committee of Wise Men on the Regulation of European Securities Markets, Brussels, 15 February 2001

¹²⁸ European Commission, Decision 2004/7/EC, *OJ L 3*, 7.1.2004, p. 32–32

¹²⁹ European Commission, Decision 2004/5/EC, *OJ L 3*, 7.1.2004, p. 28–29

¹³⁰ European Commission, Decision 2004/6/EC, *OJ L 3*, 7.1.2004, p. 30–31

¹³¹ Regulation (EU) No. 1095/2010 of the European Parliament and the Council, *OJ L 331*, 15.12.2010, p. 84–119

¹³² Regulation (EU) No. 1094/2010 of the European Parliament and the Council, *OJ L 331*, 15.12.2010, p. 48–83

¹³³ Regulation (EU) No. 1093/2010 of the European Parliament and the Council, *OJ L 331*, 15.12.2010, p. 12–47

¹³⁴ Regulation (EU) No. 1092/2010 of the European Parliament and the Council, *OJ L 331*, 15.12.2010, p. 1–11

¹³⁵ *Ibidem*, Recital (14)

¹³⁶ Regulation (EC) No. 713/2009 of the European Parliament and of the Council, *OJ L 211*, 14.8.2009, p. 1–14

Electronic Communications (BEREC).¹³⁷ The ACER is namely empowered to take decisions in relation to infrastructure affecting two or more Member States where the latter fail to agree on the relevant regulatory regimes or in case their common approach harms the internal electricity or gas markets. BEREC, on the other hand, is seeking to develop coordinated regulatory practices in Europe by fostering (through opinions) the consistency of national market remedies and the respect of NRAs for its common positions.¹³⁸ The institutional reforms in these sectors emphasise that EU regulatory systems are acquiring new types of tasks. Whereas the importance of the third generation agencies cannot be separated from the BSE crisis and risk regulation, the newer structures have responsibilities which are much more connected with operational matters, the performance of inspections and the issuing of fines. The impacts of the 2008 financial crisis are relevant to understand the context and mission of the new agencies, which operate in industries which are highly networked and where the 'spill-over' effects of uncoordinated national activities become very concerning. To be sure, the nature of the transnational links is different from one sector to the next. Whereas in energy the network dimension is related to the infrastructure, in financial services the crisis showed has shown how significant the incorporeal inter-dependencies can be. EU regulatory agencies are also acquiring tasks which very sensitive, politically. An example of this can be seen in the responsibilities of ESMA (securities) in the supervision of credit rating agencies.¹³⁹ ESMA's will be able to examine applications for registration of these agencies in Europe,¹⁴⁰ ensure non-interference with (and transparency of) ratings and methodologies;¹⁴¹ issue requests for information;¹⁴² pursue general investigations (examination of records, data and procedures);¹⁴³ conduct on-site investigations;¹⁴⁴ and impose fines.¹⁴⁵ Taking into account the extraordinary importance of concerns with the supply of capital in Europe, the ESMA power to supervise the credit rating agencies in Europe is by all means significant and emphasises that the EU has come a long way since it started to set up a few data collection agencies to support the Commission in the 1970s.

3- Considering the growth of regulatory agencies in Europe

The creation of regulatory agencies in the EU has sparked an intense debate on the substantive and institutional reasons behind this important development. The perplexity comes in part from the rather unique role of the European Commission. Whereas in national democracies the creation of regulatory agencies is normally justified by the need to 'isolate' certain regulatory activities from the daily political

¹³⁷ Regulation (EC) No. 1211/2009, *OJ L 337*, 18.12.2009, p. 1–10

¹³⁸ See: BEREC – 'Work Programme 2011' – BEREC Board of Regulators, December 2010, BoR (10) 43 Rev1

¹³⁹ Regulation (EU) No 513/2011 of the European Parliament and of the Council, *OJ L 145*, 31.5.2011, p. 30–56, Articles 15 and 21

¹⁴⁰ *Ibidem*

¹⁴¹ *Ibidem*, Article 23

¹⁴² *Ibidem*, Article 23 (b)

¹⁴³ *Ibidem*, Article 23 (c)

¹⁴⁴ *Ibidem*, Article 23 (d)

¹⁴⁵ *Ibidem*, Article 36 (a)

dynamics and party politics, in the EU the context is somewhat different and the Commission has traditionally combined its political mission with the reputation of an independent and competent technocratic body.¹⁴⁶ The question of why Europe began entrusting a series of technical but still important tasks to regulatory agencies would therefore require some other explanation.

According to Majone, the answer to this question essentially lies in the 'regulatory turn' (and vocation) of the European project. This author stresses that one of the most distinctive features of the European Union's development since the 1970s and 1980s has been the impressive growth of its regulatory competences.¹⁴⁷ Due to the rise of European health, safety, environmental, consumer protection or labour protection rules, 'regulation' became "by far the most important type of policy making in the EU."¹⁴⁸ The Commission appreciated the growing regulatory responsibilities and involvement, seeing it as a way to increase its own authority legislatively and at the implementing stages. Also, the limits of the EU budget favoured such a 'costless' move as the Community lacked resources to pursue "large-scale initiatives in the core areas of welfare-state activities – redistributive social policy and macroeconomic stabilisation".¹⁴⁹ As the workload and complexity of the Union's regulatory responsibilities increased, however, its traditional institutional machinery was not ready for the impact. Majone consequently emphasises that if the EU has become a more sophisticated and complex 'regulatory state', its affairs need to be managed through new institutions which are capable of organising the required levels of expertise, while ensuring 'credibility' and 'independence'.¹⁵⁰ Majone is therefore critical of the Commission. He emphasises the processes of politicization and 'parlamentarisation' of this institution and how the dynamics have changed and affected its regulatory capacity and reputation.¹⁵¹

Majone's defence of EU regulatory agencies can overlook the fact that the process of creating new non-majoritarian bodies can become self-reproductive. The Union may see the agencies as a way to acquire new powers and capabilities (which would also not be the most transparent of processes). This point has been made by Shapiro, who considers that the neo-functionalist inclination of the Union generated the perception that as "direct routes to further political integration are blocked [...] further growth can be achieved indirectly through the proliferation of small, limited jurisdictions, allegedly 'technical agencies' that will appear politically innocuous."¹⁵² While Member States succeeded in forcing the inclusion of national representatives in the EU agencies' management boards, the author

¹⁴⁶ See M. Shapiro, *The Problems of Independent Agencies in the United States and the European Union*, Journal of European Public Policy, Vol. 4, No. 2, 1997

¹⁴⁷ G. Majone, *The Rise of the Regulatory State in Europe*, West European Politics, Vol. 17, No. 3, 1994, pp. 77-101. See also: T. Christensen and P. Laegreid, (2006), *Agencification and Regulatory Reform* in T. Christensen and P. Laegreid, *Autonomy and Regulation: Coping with Agencies in the Modern State*, Edward Elgar, pp. 8-49

¹⁴⁸ G. Majone, *The Regulatory State and its Legitimacy Problems*, West European Politics, Vol. 22, No. 1, 1999, p. 2

¹⁴⁹ *Ibidem*

¹⁵⁰ *Ibidem*, p. 5-6

¹⁵¹ Supra 17, [Majone, 'Credibility Crisis', 2000], p. 273

¹⁵² Supra 146, [Shapiro, 'Problems of Independent Agencies', 2001], p. 281

notes that “by stressing the technical and informational functions of these agencies, by making each highly specialised to a particular technology and by incorporating large components of scientific personnel, there is undoubtedly the hope that technocrats will take over these agencies from the politicians.”¹⁵³ The unifying principle of this strategy is therefore the growing status of the EU ‘regulatory expert’ and the values of specialised knowledge and capacity which he embodies. The added importance of regulatory expertise is important for the EU as it weakens the distinction between the ‘European’ and the ‘national’. It provides the EU with a ‘single’ and clearer sense of purpose.

Regardless of more or less ‘hidden intentions’ which one may see in the proliferation of EU regulatory agencies, it is difficult to ignore some of the benefits which these bodies offer. Agencies are known to facilitate the provision of expertise in areas of high complexity and that allows the Union to acquire the capacity to address transnational challenges in contexts that are much more with complex and fluid.¹⁵⁴ Secondly, agencies also counteract the dangers of politicising the expertise. Whereas comitology represents fosters the link between technical values and ‘normative’ sensibilities as mediated by national (political) representatives; that is also not without problems and the regulatory agencies ‘may be right’ in trying to advance the best possible expert advice or decision. Considering the high levels of risk and increased level of complexity of EU regulatory activities (be it in pharmaceuticals, chemicals, transport or financial services) one might wonder why it should be otherwise. The creation of EU agencies may also improve the quality of the implementation of EU Law.¹⁵⁵ Regulatory agencies may also help to build up common views (“*communauté de vues*”) between national experts and that may then reflect on how these actors behave in their own jurisdictions.¹⁵⁶ This point is important as it suggests that the introduction of EU regulatory agencies is not something that suddenly ‘fell from the skies’; it accompanies and emphasises a shift of power from national political officials to national regulatory experts. Moreover, the agencies foster a “*communauté d’action*” as national supervisors should work out existing problems and differences within the new European structures.¹⁵⁷ While comitology also engages national actors, agencies can provide “greater stability” and “more systematic action”.¹⁵⁸ Whereas EU committees are more open to ‘wider interests’, regulatory agencies are keen on “role purification”.¹⁵⁹ The emphasis is on “expertise, autonomy and specialization of tasks in a narrow range of policy issues.”¹⁶⁰

¹⁵³ *Ibidem*. For an alternative view, focused on the importance of the managerial structures of the EU agencies (and external political controls at that level), see: D. Curtin, *Executive Power of the European Union: Law, Practices, and the Living Constitution*, Oxford University Press, 2009, p. 155-157. See also: M. Busuioc, *Accountability, control and independence: the case of European Agencies*, *European Law Journal*, Vol. 15, No. 5, 2009, pp. 599-615

¹⁵⁴ For an analysis on the advantages of regulating through agencies in the EU see: Dehousse, Joerges, Majone, Snyder and Everson, *Europe after 1992: New Regulatory Strategies*, Florence: EUI Working Paper LAW 92/31, 1992, p. 51

¹⁵⁵ *Ibidem*

¹⁵⁶ *Ibidem*

¹⁵⁷ *Ibidem*

¹⁵⁸ *Ibidem*, p. 52

¹⁵⁹ T. Christensen and P. Laegreid, (2006) *Agencification and Regulatory Reform* in T. Christensen and P. Laegreid, *Autonomy and Regulation: Coping with Agencies in the Modern State*, Edward Elgar, p. 12

The recognition of some of the advantages of EU regulatory agencies should not, however, ignore the existing risks. With regard to possible problems, two issues are often ignored. The first point concerns perhaps an excessive 'Euro-optimism'. When it is said that the national regulatory authorities should be able to work out existing differences or that the European public interest will ultimately emerge from those interactions, this may be overlooking that these regulatory agencies might display similar types of social conflicts. The notion that national or economic interests or imbalances suddenly disappear because the agencies are committed to the vales of expertise may be very illusory. These new 'EU unities' can hardly push away conflicts that are not resolvable but will introduce different ways of managing them. One of the paradoxes of modern societies "is that most interests, values, and systems are irreducibly opposed to each other: economy versus society, capital versus labour, France versus Germany".¹⁶¹ Even if communities of national experts are able to find common ground where politicians cannot (the 'problem' which has concerned Shapiro), one would have to be very optimistic to expect national supervisors to ignore the own dynamics and interests of their markets or to be indifferent to issues which are politically sensitive at the national level. Secondly, there is an issue about the internal capacity of EU agencies and *who* is proving the resources for the system to work. If we let go of the idea that there is 'perfect deliberation' within these structures, it becomes more important to understand the internal dependencies and capacity problems, and to then start looking at how existing institutional biases and problems can be controlled.

4- The dynamics of the new administrative state

The creation of regulatory agencies has important implications for the relationship between EU politics and expertise, and it also affects the way in which the national experts interact with each other and with the markets which are being regulated. Regarding the first point, we have seen above how the Courts have constrained the Commission when it receives 'expert advice' from European regulatory expertise. The fact that namely for product authorisations, the Commission cannot decide to disregard the opinion of agencies without providing equally significant *scientific* evidence in support of its preferred route of action, has the effect of associating 'science' with the European dimension strongly (which is not without risks). In such a context, regulatory expertise is not seen as being external to the EU political process (which may not decide to 'ignore' its suggestions for reasons which the former is not prepared to take into account or evaluate), but rather as something which is in-built and integral to the 'good' political decision. It was noted before that the EU seems to 'like' this because expertise does not have a national colour; it offers a common language which de-territorialises the integration process. The problem, however, is that wider social, ethical or cultural interests will still plays its role and can destabilise a form of European authority which is framed in such narrow terms. The paradox, therefore, is that because many of social tensions do not go away through institutional constraints or due to sweeping judicial rulings, what might end up having national forms of contestation of this

¹⁶⁰ *Ibidem*, p. 13

¹⁶¹ D. Chalmers, *Deliberative Supranationalism and the Reterritorialisation of Authority*, EUI Working Paper 2005/12, p. 39

regulatory science (the controversial authorisations of GMOs by the EFSA are a case in point).¹⁶² As the EU public discourse fails to accommodate the different interests and wider concerns (which cannot be expressed in scientific terms) the reaction is likely to be a 'return' to the Member States and a challenge to the authority of the EU.

With respect to the inner structure of EU regulatory expertise there is an issue about how expert interaction works within the agencies. The basic formal shape of the 'technological' controls is the international one, which ensures the presence of every national competent authority in the decision-making processes. That structure (which is the typical one in these agencies) would guarantee that each Member State' authority has a fair chance of contributing to the work, to participate in the relevant discussions, and review or criticise what the others are doing. Such a system begs questions regarding the asymmetric levels of regulatory capacity (human, financial and institutional resources) of different NRAs and to what extent that can generate imbalances in the decision-making processes. Moreover, whereas most of the regulatory agencies are based on formal equal footing of the national experts, other models favour the selection of a narrower task-force of regulatory experts which disregards the national representation principle openly (this is the case of the European Aviation Safety Agency, as well shall see in the relevant case-study chapter). That may occur as the nature of the sector and tasks are too complicated and technical for a big deliberative committee to be able to keep pace with relevant developments and efficiently organise the required expertise. Questions about this formal structure also relate to an idea of 'partial Europeanization', but in a somewhat different way.

The previous comments underline that one of the most significant aspects about the new European regulatory power relates to the notion that we may be dealing with a process of pulverisation and fragmentation of actors. The EU regulatory agencies have limited internal resources and secretariats. They structure more or less decentralised forms of interaction between the national competent authorities. The agencies also operate in market contexts which are particularly fluid and dynamic and where, therefore, the involvement with the sector can be quite important. One of the effects which can have is that it becomes unpredictable where the power will be, who will have the important resources to make the regulatory system work effectively and how the internal division of labour is to be organised. To be sure, the challenge here does not simply concern the 'national identity' of the expertise but the way in which the European agencies communicate with market activities that are highly fluid and dynamic. It would appear that, in such contexts, it becomes more important to ensure intimate relationships with the sectors and to develop institutional structures and tools which are well adapted to the specific characteristics of the markets. The link between the European regulatory agencies and new product authorisations ('one-off' technical assessments) is relevant in this regard. Where they deal with product licensing, the EU agencies are usually concerned with the evaluation of particularly innovative substances (e.g. pharmaceuticals or food sectors) which are associated with

¹⁶² On this see: D. Chalmers, *Risk, Anxiety and the European Mediation of the Politics of Life*, *European Law Review*, Vol. 30, 2005, p. 649-675

higher levels of uncertainty and complexity. The institutional effects of these product assessments can be important for they increase the constraints on those which are meant to check the 'initial' scientific assessments, through EU 'peer reviews' for example.

The emergence of regulatory agencies in the EU is also associated with a set of de-legalisation dynamics. In EU aviation safety, for example, while the EASA 'certification specifications' (which set down this agency's own understanding on how the safety rules should be complied with by the industry) only represent this agency's opinion, respect for such standards leads to a presumption of compliance with the law. While their status remains unclear, 'soft' regulatory instruments still set market expectations and may involve consequences of high importance for those affected by these decisions. Reliance on soft law instruments of regulation reflects a conscience of the limits of command-and-control regulation and signals a closer involvement with complex and fast-moving markets where it is important to ensure flexibility, adaptability and responsiveness to change. The de-formalisation of European regulation can (according to Joerges) be seen as threatening the very idea of integration through law and the guarantees that this is supposed to offer to those affected by that power.¹⁶³ Alternatively, he says, one might consider a more modest place for EU law: the European legal system should acknowledge its integrative limits. Where it cannot regulate on the basis of political mediation or without weakening legal guarantees for third parties, the 'relative autonomy of the state' in handling the relevant conflicts should be recognised.¹⁶⁴ One of the difficulties with this approach, however, is that in many cases the use of soft laws by EU regulatory authorities is used to precisely to challenge more serious problems of coordination in contexts where the level of decentralisation is higher. With regard to the aviation safety example provided above, the ('soft') certification specifications already existed before they became part of the EU legal system; they were organised and worked out through international frameworks (in this case via the Joint Aviation Authorities, as we shall see in the EASA case-study chapter). In a context such as this, the concerns about the use of soft laws in Europe do not go away, but the 'autonomy' of the Member States is also an illusion.

5- The mechanics of formal accountability

The growing status and authority of the EU regulatory agencies raises the fear that we may be lacking equally significant controls on their powers. As we shall see below, the literature's response has been that strengthened *ex post* checks on these bodies may be needed. Meanwhile, the focus on formal accountability has diminished attention vis-à-vis the dynamic aspects of the regulatory systems' institutional life. One may wish to distinguish between three types of threats to the effectiveness of the controls 'of the state' (i.e. judicial review and parliamentary reviews) in the context of the new EU regulatory state. They may face a problem of 'exclusion' (e.g. soft laws escaping the judicial process,

¹⁶³ See C. Joerges, *Integration through de-legalisation? An irritated heckler*, European Governance Papers (EUROGOV), 2007, No N-07-03, online: <http://www.connex-network.org/eurogov/pdf/egp-newgov-N-07-03.pdf>

¹⁶⁴ *Ibidem*, p. 13

regulatory tasks too quick or fluid for Parliaments or Courts to intervene and to do so effectively). Such *ex post* controls may also encounter a ‘dependence’ or ‘incapacity’ problem due to the strong reliance on regulatory systems for the implementation of EU law. Moreover, the Courts and the EP are heavily reliant on the information and expert analyses provided by the agencies in their questioning exercises.¹⁶⁵ Thirdly, those checks confront a risk of ‘marginalisation’ or ‘irrelevance’ because the dynamics of the EU regulatory agencies can create internal risks (notably in terms of the functioning of a regulatory state that is fundamentally de-centralised) that are impermeable through *ex post* reviews on the ‘expertise’. Whereas the first two dimensions (‘exclusion’ and ‘dependence’) have deserved attention from the literature, the final (‘irrelevance’) point has been underplayed or simply ignored as it has been assumed that the internal (techno-)controls are working well. This is a critical issue, however, suggesting that the regulatory agencies raise new types of concerns and that we may be lacking the administrative law tools to deal with those issues.

Judicial controls on EU regulatory agencies

One of the concerns with the creation of EU agencies is that judicial controls on their power may be weak. Former Article 230 EC did not include agencies in the list of EU bodies the acts of which could be subject to judicial review. As we shall below, this gap has been addressed by the Lisbon Treaty, and it is now explicitly accepted that acts of EU agencies (intended to produce legal effects vis-à-vis third parties) fall within the jurisdiction of the Court (Article 263 TFEU).

Before ‘Lisbon’, the Courts therefore had to decide what to do in cases where agencies’ decisions affected third parties, whether or not to afford them protection. This issue was considered by the General Court (then CFI), in *Sogelma*, where it was asserted that “any act of a Community body intended to produce legal effects vis-à-vis third parties must be open to judicial review”.¹⁶⁶ *Sogelma* concerned a case directed against the European Agency for Reconstruction (EAR) relating to tender procedures. The EAR was managing a number of programmes for the reconstruction of Serbia and Montenegro, which included preparing and assessing invitations to tender and awarding contracts. *Sogelma* had submitted a tender (following a procurement noticed issued by EAR) but the Agency ended up cancelling this tender procedure since “none of the offers received was technically compliant.”¹⁶⁷ The General Court considered that the cancellation of the tender by EAR fell under its jurisdiction, by analogy with *Les Verts* (i.e. the principle of judicial review ‘of any act of a Community body intended to produce legal effects vis-à-vis third parties’).¹⁶⁸ The Court noted that while *Les Verts* concerned “Community institutions” and not agencies, the situation of bodies “endowed with the power to take measures intended to produce legal effects vis-à-vis third parties is identical” to that

¹⁶⁵ For an analysis of the challenges of judicial controls on EU regulatory expertise see: A. Alemanno, *EU Risk Regulation and Science: The Role of Experts in Decision-making and Judicial Review* (2008), Chapter 2 in Ellen Vos (ed.), *European Risk Governance: Its Science, its Inclusiveness and its Effectiveness*, CONNEX Report Series, Nr 06, ISSN 1864-1539/6

¹⁶⁶ Case T-411/06 *Sogelma v EAR*, ECR 2008 Page II-02771, at paragraph 37

¹⁶⁷ *Ibidem*, paragraph 11

¹⁶⁸ Case 294/83 *Parti écologiste "Les Verts" v European Parliament*, ECR 1986 Page 01339

case; and it was hence not acceptable that in a Community of law “such acts escape judicial review”.¹⁶⁹ The applicant had effectively lost, as a consequence of EAR’s decision, the possibility of being awarded the relevant contract. Moreover, if judicial protection was not ensured in this case the applicant would be denied a right that would otherwise exist if it had been the Commission (instead of an agency) the one taking these measures.¹⁷⁰

Sogelma was (it should be remembered) decided at the time of the European Community. Even if the reasoning in this case was to be accepted, there were still questions about the opportunities for judicial review with respect to the (former) third-pillar agencies, in an area where the Court had limited jurisdiction.¹⁷¹ That problem was considered in *Spain v. Eurojust* (which was in fact delivered before *Sogelma*).¹⁷² The case concerned an application for annulment under former Article 230 EC brought by Spain against Eurojust for language requirements with respect to individuals’ applications for the post of librarian/archivist in that agency. For the Advocate General (Poiáres Maduro), while Spain could not rely on Article 230 EC to seek the annulment of the contested acts as these were adopted under Title VI of the Treaty on European Union; “in a *Union governed by the rule of law*, it is essential for measures of Union institutions and bodies to be amenable to review by a Union Court, so long as they are intended to produce legal effects vis-à-vis third parties.”¹⁷³ [Emphasis original] However, the admissibility of an action brought by a Member State, under these conditions, could be contested. The affected parties (candidates for the posts in Eurojust) had access to the Court of First Instance under EU Staff Regulations. The Court therefore ruled that it was sufficient that the concerned acts could be brought within its jurisdiction through the intervention of the aggrieved parties for the requirement of effective judicial protection to be met in this case.¹⁷⁴

The entry into force of the Lisbon Treaty has confirmed the importance of judicial review of EU agency acts (but it also creates new problems, as we shall see below). The new Article 263 TFEU is reproduced here:

The Court of Justice of the European Union shall review the legality of legislative acts, of acts of the Council, of the Commission and of the European Central Bank, other than recommendations and opinions, and of acts of the European Parliament and of the European Council intended to produce legal effects vis-à-vis third parties. It shall also review the legality of acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties.

¹⁶⁹ Supra 166, [*Sogelma*], paragraph 37

¹⁷⁰ For an analysis of this case, see: T. Tridimas, *Community Agencies, Competition Law, and ECSB Initiatives on Securities Clearing and Settlement*, p. 249 in P. Eeckhout and T. Tridimas (eds.), *Yearbook of European Law 2009*, Vol. 28, Oxford University Press, 2010

¹⁷¹ See D. Chalmers, *European Union Law*, 1st edition, Cambridge University Press, 2006, p. 120-121

¹⁷² Case-160/03 *Spain v. Eurojust*, ECR 2005 Page I-02077

¹⁷³ Opinion of Advocate General Poiáres Maduro, *Spain v Eurojust* (Case C-160/03), delivered on 16 December 2004, at paragraph 17

¹⁷⁴ Supra 172, [*Spain v Eurojust*], paragraph 42

Moreover, the Court of Justice will be able to review the regulatory agencies' "failure to act" (Article 265 TFEU):

Should the European Parliament, the European Council, the Council, the Commission or the European Central Bank, in infringement of the Treaties, fail to act, the Member States and the other institutions of the Union may bring an action before the Court of Justice of the European Union to have the infringement established. This Article shall apply, under the same conditions, to bodies, offices and agencies of the Union which fail to act.

The new Article 263 TFEU means that Courts will now have to consider what the provision allows them to do, what type of acts can be considered to generate *legal* effects on third parties. There are both legal and institutional constraints which have to be taken into account in this context. It is not clear, for example, that the Courts may (or will) review acts of EU agencies which directly imply consequences for third parties but which only 'prepare' subsequent regulatory measures (in the context of an authorisation procedure, for example). Judicial intrusions in the inner world of EU agencies may also have to be limited to avoid litigation from being systematically used by powerful social and economic interests wishing to challenge all sorts of regulatory deliberations that somehow affect them in a way which they do not like.

There is, in addition, a question related to judicial review of agency *opinions* to the European Commission. Before the Lisbon Treaty was introduced, the status of those opinions and the role of Courts in their review were considered. This happened in *Artegodan*; a case which emerged after the Commission decided to withdraw the marketing authorisations of a number of medicines used to treat obesity (anorectics).¹⁷⁵ The General Court observed that the Commission decision only confirmed the scientific opinion issued by the European Medicines Agency's main scientific body: the Committee for Human Medicinal Products (CHMP). The Commission itself did not have the resources which would have allowed it to conduct the required scientific assessments and so the reliance on the CHMP's opinions was needed for the Commission to decide on such matters.¹⁷⁶ The Court also considered that whereas the scientific recommendation did not formally bind the Commission, it was "extremely important so that any unlawfulness of that opinion must be regarded as a breach of essential procedural requirements rendering the Commission's decision unlawful."¹⁷⁷ The judiciary was therefore entitled to review both the formal legality of the CHMP's scientific opinion and the Commission's exercise of discretion.¹⁷⁸ Regarding the first point, the Court considered that it should review the proper functioning of the Committee, the internal consistency of the opinion and the statement of reasons.¹⁷⁹ This enables the Court to namely "examine whether the opinion contains a

¹⁷⁵ Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00, & T-141/00 *Artegodan GmbH and Others v Commission*, ECR 2002 Page II-04945

¹⁷⁶ *Ibidem*, paragraph 198

¹⁷⁷ *Ibidem*, parag 197

¹⁷⁸ *Ibidem*, parag 199

¹⁷⁹ *Ibidem*, parag 200

statement of reasons from which it is possible to ascertain the considerations on which the opinion is based, and whether it establishes a comprehensible link between the medical and/or scientific findings and its conclusions.”¹⁸⁰ The scientific committee was hence “obliged to refer to the main reports and scientific expert opinions on which it relies and to explain, in the event of discrepancy, the reasons why it departed from the conclusions of the reports or expert opinions supplied by the undertaking concerned.”¹⁸¹ What the Court could not do, however, was substitute its own views for those of the Committee.¹⁸² This judicial approach was later confirmed in *Oliveri*.¹⁸³

Despite of where the new Article 263 TFEU might take us, it may be difficult for the Courts to do more than stick to this notion of a scientific due process when looking at EU agency ‘opinions’. The complexity and dynamism of the new administrative state warns Courts about the dangers of trying to second-guess the agencies’ expert advice. The features of this new power also suggest that the Court’s concerns with the integrity of the ‘technological’ process essentially highlight a (legal) concern with formal interactions within the Agency. This is different from actually considering how the procedures work (in their own terms) and to look at what the substantive institutional risks are.

The Parliamentary controls on EU regulatory agencies

The rising profile of EURS has led many to believe that it would be advisable to refine and strengthen the existing political accountability processes in relation to these bodies. For Griller and Orator, for example, the accountability of EU agencies could be fashioned in accordance with the model of the European Central Bank (which is based on regular parliamentary reporting and hearings) and further “surveillance mechanisms” of the European Parliament, the Council, and the Commission vis-à-vis agencies be enhanced.¹⁸⁴ The Parliament’s control of the regulatory agencies touches on both the performance of the technical work and on budgetary/financial related matters.¹⁸⁵ Regarding the regulatory activities as such, the Parliament scrutinises annual reports and conducts hearings in specialised committees. A study concludes that the “intensiveness with which [the EP] makes use of the various arrangements at its disposal varies significantly from one committee to the next”.¹⁸⁶ The political accountability of EU regulatory agencies is also said to be “sketchy and sporadic”, focused on a “limited number of issues” and “driven by political priorities.”¹⁸⁷ On the other hand, it is said that “it is

¹⁸⁰ *Ibidem*

¹⁸¹ *Ibidem*

¹⁸² *Ibidem*

¹⁸³ Case T-326/99 *Nancy Fern Oliveri v Commission and European Agency for the Evaluation of Medicinal Products*, ECR 2003 Page II-06053. For an analysis of this case see: M. Busuioc, *The Accountability of European Agencies, Legal Provisions and Ongoing Practices*, Eburon (2010), p. 175-176

¹⁸⁴ Griller and Orator, *Everything under control? The “way forward” for European agencies in the footsteps of the Meroni Doctrine*, European Law Review, Vol. 35, No. 1, 2010, p. 13

¹⁸⁵ M. Busuioc, *The Accountability of European Agencies, Legal Provisions and Ongoing Practices*, Eburon, 2010, p. 98

¹⁸⁶ *Ibidem*, p. 130

¹⁸⁷ *Ibidem*, p. 131

in situations of 'fire alarms' that the merit and value of these forums can be found."¹⁸⁸ The MEPs failure to monitor the daily work of the agencies may (according to the author) be compensated for "in situations of crisis or where serious problems involving a particular agency come to the public eye."¹⁸⁹ The fact that the Parliament 'wakes up' after a public crisis has emerged is not a compliment, however, to its accountability credentials. The question would also have to be why the Parliament was incapable of identifying the problem beforehand and whether its intervention makes much of a difference in those circumstances, considering that under 'alarming' scenarios the relevant agency might have a strong incentive to look into and remedy what has possibly gone wrong.

The European Parliament also has responsibilities in the supervision of the regulatory systems' budgetary and financial life. Through the discharge procedure, the Parliament is asked to politically approve the implementation of the agencies' budgets.¹⁹⁰ If the Parliament believes there is a problem, it may postpone or refuse the discharge.¹⁹¹ This happened for the first time in May of 2011, when the Parliament decided to postpone the 2009 budget discharge for the EMA and the European Police College (CEPOL).¹⁹² Whereas the CEPOL's case concerns a "persistent lack of compliance with the Financial Regulation", the EMA's condemnation questions the independence of its experts, its hiring practices and warns about conflicts of interest with the pharmaceutical industry.¹⁹³ The MEPs consider that "there was no proper guarantee of the independence of experts hired to carry out scientific evaluations of human medicines and that some experts had conflicting interests in the case of the evaluation of the anorectic Benfluorex."¹⁹⁴ They are particularly worried about the "very late withdrawal from the market" of this substance (commonly known as 'Mediator'), a sleeping pill which was taken from circulation in 2009 due to risky side-effects.¹⁹⁵ The Parliament's comments arguably damage the public image and reputation of EMA. It is unclear, however, whether this demonstration of force by the Parliament was based on solid evidence against the EMA (and will be consequential) or whether it reflects other types of institutional concerns. The Parliament's decision to postpone the approval of EMA's budget only happened after the withdrawal of mediator from the market and followed much public criticism directed at the EMA for its handling of this case.¹⁹⁶ It is therefore tempting to see this alarm with regard to EMA as a sign of a weakness on an institution which for

¹⁸⁸ *Ibidem*

¹⁸⁹ *Ibidem*

¹⁹⁰ *Ibidem*, p. 152

¹⁹¹ *Ibidem*, p. 155

¹⁹² European Parliament – 'Press Release: 2009 budget discharge: Police College, Medicine Agency and Council postponed', available at: <http://www.europarl.europa.eu/en/pressroom/content/20110510IPR18991/html/2009-budget-discharge-Police-College-Medicine-Agency-and-Council-postponed>

¹⁹³ *Ibidem*

¹⁹⁴ *Ibidem*

¹⁹⁵ European Medicines Agency – 'Press Release: EMA recommends withdrawal of benfluorex from the market in European Union', 18 December 2009, EMA/CHMP/815033/2009

¹⁹⁶ See: European Medicines Agency – 'Benfluorex: summary background on discussions at CPMP (1998), PhVWP (1998-2003) and CHMP (2009)', 18 May 2011, EMA/394445/2011. See also: euobserver.com, 'EU drugs regulator accused of being too cosy with big pharma', 11/5/2011, available at: <http://euobserver.com/9/32309>

more than fifteen years of this agency's existence never once questioned its internal procedures or the quality of its practices.

Overall, the push for bolder parliamentary controls with regard to European regulatory agencies may overlook the lack of resources and expertise of this institution to carry out that mission well. The Parliament's difficult experience in the context of the control of the Commission's implementing measures (comitology) deserves to be remembered, in this context. As explained above, the Parliament spent many years and invested much political energy in its attempt to be granted equal footing vis-à-vis the Council in the supervision of the workings of the committee system. Once it got those powers, however, it failed to use them. As noted elsewhere, in 2008 "the committees gave 2,185 opinions but only seven references were made to the Council."¹⁹⁷ Moreover, data on the operation of the regulatory procedure with scrutiny shows that only in very few cases has the Council or the Parliament vetoed the draft Commission measures. In 2008, for example, "seven measures were vetoed by one or other of the institutions on the grounds that the Commission was exceeding its powers, just under 10% of the measures proposed for regulatory procedure with scrutiny in that year."¹⁹⁸ These numbers also indicate that "it is the Council that has benefited most from the procedure, not the Parliament, vetoing all but one of them."¹⁹⁹ Overall, the important constraints in comitology can hence be found 'within the process', in the relationship between the Commission and the committees, as the work of Joerges and Neyer has managed to show.²⁰⁰ Studying the interaction between the Commission and the Standing Committee on Foodstuffs (StCF) and the Scientific Committee on Foodstuffs (SCF), they saw that comitology did not involve national checks on the Commission but worked alongside more fluid and problem-solving lines, generating an "Europeanized inter-administrative discourse characterised by mutual learning and an understanding of each other's difficulties in the implementation of specific solutions."²⁰¹ Considering the higher levels of complexity and sophistication of the market activities with which the EU regulatory agencies have to engage with (in comparison with comitology), the suspicion that the EU institutions do not have the resources to police the operation of the agencies can only be stronger.

European Ombudsman

There have also been calls to strengthen the accountability of EU regulatory networks through the European Ombudsman.²⁰² While the Ombudsman is a "modest entity, with much to be modest about" (8 million Euros of budget and approximately 60 staff); some see the soft, flexible and more informal

¹⁹⁷ Supra 4, [Chalmers et al, 2010], p. 122

¹⁹⁸ *Ibidem*, p. 120-121

¹⁹⁹ *Ibidem*

²⁰⁰ C. Joerges and J. Neyer, *Transforming Strategic Interaction into Deliberative Problem-Solving: European Comitology in the Foodstuffs Sector*, Journal of European Public Policy, Vol. 4, No. 4, 1997, p. 618-620

²⁰¹ *Ibidem*

²⁰² C. Harlow and R. Rawlings, *Promoting Accountability in Multilevel Governance: A Network Approach*, European Law Journal, Vol. 13, No. 4, 2007, p. 556

nature of its mandate as an advantage in control of these supranational systems of networking.²⁰³ The mission of the EO is informed by the following (main) characteristics: 1) “the free and easy access for the citizen”; 2) the “primary focus on the handling of complaints” (which is accompanied by “the power to recommend not only redress for individuals but also broad changes to laws and administrative practices”); 3) “use of proactive means” (i.e. own-initiative inquiries and guidance to public officials on how to manage the relationship with the public); 4) “effectiveness based on moral authority, cogency of reasoning and ability to persuade public opinion, rather than power to issue binding decisions”; and 5) “broad review function that can encompass legal rules and principles, the principles of good administration, and human rights.”²⁰⁴ Differently from the Courts, the Ombudsman “rightly stresses the value of a complaints service that is not only free of charge at the point of delivery but also free from strict standing rules and relatively swift.”²⁰⁵ Unlike the judicial process the Ombudsman has a much more conciliatory, mediatory and balancing logic.²⁰⁶ This reduction in formalism means that the intervention of the Ombudsman ensures, at least, that the target EU body provides reasons for its approach or decision.²⁰⁷

The scrutiny of the Ombudsman in relation to EU regulatory systems tends to be dominated with personnel issues and access to documents disputes. In some cases, however, the Ombudsman’s intervention has had important substantive implications.²⁰⁸ In a case lodged in 2007, two researchers of the Nordic Cochrane Centre applied for access to clinical study reports and protocols for trials of rimonabant (brand name: ‘Acomplia’) and orlistat (brand name: Xenical, Alli), both of which are anti-obesity medicines.²⁰⁹ While the manufacturers of these products had submitted this data to the EMA for the purposes of obtaining a marketing authorisation, the Agency has traditionally refused the publication of clinical trials information with the argument that this would threaten the commercial interests of the companies. The complainants argued that such information “was important for patients because anti-obesity pills are controversial” and that “the effect on weight loss in the published trials is small, and the harms are substantial.”²¹⁰ The EMA insisted that the information was commercially sensitive and that there was no ‘overriding public interest’ in the disclosure.²¹¹ The Ombudsman then proposed a ‘friendly solution’ which asked the EMA to grant access to the required data or else provide good reasons why that should be denied. After the EMA failed to comply, the

²⁰³ *Ibidem*

²⁰⁴ N. Diamandouros, Speech to the Fifth Seminar of the National Ombudsmen of the EU Member States (2005), available here: <http://www.ombudsman.europa.eu/activities/speeches.faces>

²⁰⁵ *Supra* 202, [Harlow and Rawlings, 2007], p. 555

²⁰⁶ P. Magnette, *Between Parliamentary Control and the rule of Law: the Political Role of the Ombudsman in the European Union*, *Journal of European Public Policy*, Vol. 10, No 5, 2003, p. 682

²⁰⁷ *Supra* 185, [Busuioc, 2010], p. 198 and 199

²⁰⁸ *Ibidem*, p. 199-202

²⁰⁹ The two researchers describe their access to EMA documents story (and consider its implications) here: P. Gøtzsche and A. Jørgensen, *Opening Up Data at the European Medicines Agency*, *British Medical Journal*, 2011; 342:d2686

²¹⁰ *Ibidem*

²¹¹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council, *OJ L 145, 31.5.2001, p. 43–48*, Article 4 (2)

Ombudsman put forward a second friendly solution proposal (asking the EMA to clarify its position).²¹² Finding no positive response, the Ombudsman went to the EMA to inspect the relevant documents.²¹³ Finally, in a very critical draft recommendation the Ombudsman concludes that “there appears to be nothing to suggest that disclosure would *specifically and actually* undermine commercial interests.”²¹⁴ [Emphasis original] Moreover, the Ombudsman “finds that the EMA’s refusal to grant access to the requested documents constituted an instance of maladministration”.²¹⁵ The EMA then informed the Ombudsman that it would grant access to the requested documents.²¹⁶ In a British Medical Journal article, the two doctors describe their story and accuse the EMA of “protecting the profits of the drug companies ahead of protecting the lives and welfare of patients.”²¹⁷ They also note that their case “sets an important precedent” as on November of 2010 the EMA announced that it “would widen public access to documents, including trial reports and protocols.”²¹⁸ While this case started off as an access to internal documents dispute, its wider implications became clear as the EMA resisted with all its strength to cooperate with the Ombudsman (until it finally ‘gave up’).

In other situations the effectiveness of the Ombudsman is inevitably more limited. In a case which also concerned the medicines agency (EMA), a German company that was in the business of selling homeopathic veterinary medicines applied for the establishment of maximum residue limits for two substances and their consequent inclusion in the annexes of a Council Regulation.²¹⁹ The EMA’s veterinary committee (CVMP) rejected this with the argument that the safety profile of these substances was known to be problematic. When deciding on the case, the Ombudsman considered that it was “not in a position to decide whether the [EMA] could have adopted a less strict approach towards the substances concerned” and that “this question could ultimately only be decided by the Community courts.”²²⁰ The Ombudsman therefore concludes by noting that “in the light of the need to protect the health of consumers the attitude of the EMA cannot be regarded as constituting maladministration.”²²¹ This case serves to show that the mission of the Ombudsman is mainly focused on instances of maladministration. It also has a strong human rights focus. The resources of the Ombudsman are quite limited (as explained above), and there is also an issue about the lack of expertise of the Ombudsman in contexts where level of complexity of the matters is very high and requires some degree of specialised knowledge. On the other hand, the Ombudsman may still offer some interesting opportunities as a means to ensure that the ‘internal process’ of the regulatory

²¹² Supra 209, [P. Gøtzsche and A. Jørgensen]

²¹³ *Ibidem*

²¹⁴ European Ombudsman – ‘Draft Recommendation in his inquiry into complaint 2560/2007/BEH against the European Medicines Agency’, p. 12

²¹⁵ *Ibidem*, p. 12-13

²¹⁶ Supra 209, [P. Gøtzsche and A. Jørgensen], p. 2

²¹⁷ *Ibidem*, p. 3

²¹⁸ *Ibidem*, p. 4

²¹⁹ European Ombudsman – ‘Decision on complaint 1193/99/GG against the European Agency for the Evaluation of Medicinal Products’, 3 March 2000

²²⁰ *Ibidem*, point 1 of Decision

²²¹ *Ibidem*

agencies can be checked on and protected if and where there is a risk of an institutional imbalance within the system.

EU regulatory agencies and the new institutional concerns

The increased complexity and sophistication of modern EU governance begs questions about the institutional capacity of the regulatory agencies to deal with the existing challenges. European regulatory agencies have limited resources, they tend to have relatively small secretariats, and essentially organise more or less decentralised forms of cooperation between twenty-seven different national competent authorities. The sectors that are being targeted by these agencies are also very dynamic and fluid ones. The regulation of new market activities in financial services, the approval of novel aircraft type-models, the licensing of new medicinal products or the supervision over thousands of chemicals substances marketed across Europe are all tasks which require unparalleled levels of EU engagement with the sectors and in many ways transform how the administration of 'Europe' operates. In this context, there are important questions about the resources of the EU regulatory structures, the extent and nature of the reliance on national expertise to carry out the work and on the way in which the connection with the own dynamics of the sector develops. If EU agencies in fact lack internal resources, there will be an issue regarding *who* is providing the human, financial or institutional means for the system to work and whether (and how) such a dependence can be worrying from the perspective of the 'European public interest'. In such a context, one may wonder whether calls for more political and judicial constraints on EU regulatory agencies can actually deal with the problems of the new administrative state. By emphasising (static) formal controls on the agencies, there is a risk of diverting attention from the peculiar structure of these bodies as well as from the dynamic challenges associated with this power.

In the subsequent chapters, the thesis explores these issues in the context of four EU regulatory agencies: the European Medicines Agency (EMA), the European Chemicals Agency (ECHA), the European Securities and Markets Authority (ESMA) and the European Aviation Safety Agency (EASA). We will see that the dynamics of each of those bodies creates a series of dysfunctions and that the available ways of controlling them are unsatisfactory. It will also be shown that the institutional concerns emerging from each of those case-studies are different and peculiar; each sector raises its own set of risks. The case-study chapters shall, in addition, consider possible solutions to the difficulties which they identify. Those individual proposals will then be examined (further) and 'brought together' in the Conclusion of the thesis, where an attempt is made to develop a common framework to deal with the problems of the new administrative state of the EU.

Chapter II

New risks and institutional imbalances: the European Medicines Agency's centralised procedure for medicines authorisation

Introduction

In 1995 the European Union decided to introduce a “centralised procedure” for the evaluation and authorisation of medicinal products.²²² It also established an agency (the European Medicines Agency) to coordinate the operation of this procedure and submit opinions to the Commission.²²³ The centralised procedure offers pharmaceutical companies the possibility of submitting a single application for a marketing authorisation, which (if accepted) is valid throughout the territory of the Union. The application is sent to the European Medicines Agency (EMA) and the latter conducts the scientific assessment of the product. The EMA cannot itself grant marketing authorisations but makes proposals to the Commission, which formally decides on this (although, in practice, the Commission has always supported the EMA marketing authorisation recommendations).²²⁴ The centralised procedure was established (we shall see) mainly due to problems of trust between the national competent authorities and as a consequence of institutional failures in the workings of the mutual recognition procedures. Importantly, though, while the remit of the centralised procedure has been formally broadened in more recent reforms, the scope of this procedure is limited and essentially covers medicinal products which are new or that involve some relevant aspect for society. The centralised procedure is therefore linked to a particular type of product (where innovation is important). On the other hand, most medicines in Europe continue to be authorised either via national procedures, or through mutual recognition or decentralised processes.

Institutionally, the mechanics of the centralised procedure are more decentralised than they might otherwise appear. When the EMA receives an application for a marketing authorisation (human medicines), the scientific assessment of that product is not performed ‘in London’ (where the EMA is based), but is given to a Member State ‘Rapporteur’, which then reports the results back to the Agency’s Committee for Medicinal Products for Human Use (CHMP) – where each national competent authority is represented (and the Rapporteur is chosen from the members of this committee).²²⁵ The process might also include a Co-Rapporteur, which performs a ‘second’ scientific assessment of the product, independently from the Rapporteur. The Rapporteur and Co-Rapporteur then have to share their own ‘initial’ assessments with the CHMP, for deliberation. The chapter considers the workings of these ‘scientific’ interactions by examining how the EMA decided on two

²²² Council Regulation (EEC) No 2309/93, *OJ L 214*, 24.8.1993, p. 1–21. This has been replaced by: Regulation (EC) No 726/2004 of the European Parliament and of the Council, *OJ L 136*, 30.4.2004, p. 1–33

²²³ *Ibidem*

²²⁴ Regulation (EC) No 726/2004 of the European Parliament and of the Council, *OJ L 136*, 30.4.2004, p. 1–33, see Article 57

²²⁵ *Ibidem*, Article 78

medicines (Acomplia and Champix) – both of which were evaluated and authorised through the centralised procedure. It will be shown that the initial assessment of the Rapporteur has a very strong impact on the outcome of the product's assessment and that 'checks and balances' within this system (via the CHMP) have become diluted. The link between the centralised procedure and the scientific evaluation of *new* substances (such as Acomplia and Champix) is important to understand why that happens. These 'one-off' product assessments are associated with higher levels of scientific uncertainty (as there is no past experience with these medicines) and promote an institutional model which is more fluid and less stable. There is also a risk that, ultimately, the scientific work produced by the EMA will (as a consequence of these pressures) end up being of a lower quality.

The chapter is structured as follows: first, the emergence of EU regulation in the pharmaceuticals sector is considered. Secondly, the reforms to the centralised procedure introduced in 2004 shall be assessed. The third section examines the reasons behind the mitigated impact of those reforms and relates that to the nature of the centralised procedure 'product'. Fourthly, the importance of the Rapporteur and the issue of regulatory capacities will be developed. The subsequent section investigates the dynamics of deliberation in the CHMP. Finally, the relationship between the EMA and the Commission will be explored. The chapter concludes with a reflection on how the new type of problems emerging from the operation of the centralised procedure could be managed.

1- The emergence of EU regulation of pharmaceuticals

It is difficult to address the EU regulation of pharmaceuticals without recognising the impact of the Thalidomide disaster, in the early 1960's. Thalidomide is a sedative that was designed to help pregnant women when suffering from morning sickness. Tragically, the use of this drug led to the birth of thousands of deformed babies. This crisis exposed the inadequacies of safety control mechanisms and shaped the regulation of the medicines sector in the decades to come. In a time where pharmaceutical scientific research progressed and international trade flows increased, the existing regulatory regimes were inadequate to face the nature of the risk involved.²²⁶ The lack of regulatory cooperation at the European and International level also surfaced as a major issue.

Within the European context, the Commission took initiative and decided to tackle the existing diversity in regulatory assessments and evaluation systems between the Member States. With the approval, in 1965, of the first European piece of legislation in the pharmaceuticals sector, the EU was pursuing three main lines of action: 1) it clarified what a 'medicinal product' was considered to be; 2) established that a drug would only be approved for marketing if accompanied by documentation in support of its safety, effectiveness and therapeutic value; and 3) laid down a number of common rules guiding testing requirements and labelling.²²⁷ As Permanand observes, the emphasis of these reforms

²²⁶ See: J. Feick, *Regulatory Europeanization, National Autonomy and Regulatory Effectiveness: Marketing Authorization for Pharmaceuticals*, MPIfG Discussion Paper 02/6, p. 9

²²⁷ Council Directive 65/65/EEC, *OJ 22, 9.2.1965, p. 369–373*

“[...] was decidedly on product safety and efficacy”.²²⁸ The degree of EU involvement in the pharmaceutical sector was still, in any case, at a very embryonic stage.

A new wave of legislative intervention came ten years later, in 1975.²²⁹ The Directives approved at the time introduced three important changes. First, they developed a set of detailed common rules to standardise the tests and trials that medicinal products were subject to in the European Union. Secondly, a multi-state mutual recognition procedure was established, whereby a company which had received authorisation to market a certain medicine in a Member State could seek the recognition of that authorisation in at least five other Member States.²³⁰ Thirdly, a Committee for Proprietary Medicinal Products (CPMP), including representatives of the Commission and national authorities, was created with the objective of supervising the multi-state application process and submit an opinion on whether medicines subject to that procedure complied with the requirements laid down by Council Directive 65/65/EEC.²³¹ The procedure worked as follows: once a marketing authorisation had been sent to at least five Member States, the competent authorities of those Member States were given a period of 120 days to approve the drug or raise objections.²³² Where the Member States objected, the CPMP had to be notified. Within 60 days the CPMP would then have to submit an opinion on the matter.²³³ The national authority which had raised concerns, however, was not bound to the position expressed by the CPMP.

This new system of drug authorisation did not meet the Commission's expectations. In fact, according to the Commission, “[t]his procedure was hardly used by the pharmaceutical industry.”²³⁴ Between 1978 and 1985 only 41 applications were made under the multi-State application procedure.²³⁵ The Commission was also concerned with the slowness of the decision-making process. While half of the national authorisation decisions were taken in the year following the opinion of the CPMP, the Commission considered that it was “worrying to note that the other half of definitive decisions have taken more than 1 year and as much as 4 years in extreme cases, after the opinion of the Committee.”²³⁶

It was in the context of this frustration that the Union (then Community) introduced, in 1987, a ‘concertation procedure’ for high technology medicinal products (in particular those derived from

²²⁸ G. Permanand, *EU Pharmaceutical Regulation – The Politics of Policy-Making*, Manchester University Press, 2006, p. 49

²²⁹ Council Directive 75/318/EEC of 20 May 1975, *OJ L 147*, 9.6.1975, p. 1–12. Second Council Directive 75/319/EEC of 20 May 1975, *OJ L 147*, 9.6.1975, p. 13–22

²³⁰ Second Council Directive 75/319/EEC of 20 May 1975, *OJ L 147*, 9.6.1975, see Article 9

²³¹ *Ibidem*, Article 8

²³² *Ibidem*, Article 10(1)

²³³ *Ibidem*, Article 11(1)

²³⁴ European Commission, ‘Report from the Commission on the Activities of the Committee for Proprietary Medicinal Products’, COM (88) 143 Final, Brussels 22 March 1988, p. 10

²³⁵ *Ibidem*

²³⁶ *Ibidem*, p. 11

biotechnological processes).²³⁷ As the Commission observed at the time, this new framework “[differed] fundamentally from the multi-state procedure in that, it is applicable prior to any national decisions concerning high technology medicines...”²³⁸ Indeed, once a Member State had received an application for a marketing authorization of a medicine developed by means of a new biotechnological process, the national authorities would be required to bring the matter before the CPMP for an opinion.²³⁹ The final responsibility for the decision, however, still rested with the Member State concerned.

Despite these efforts the fact was that attempts to standardise the national authorisation processes for medicines had not been successful. Whether it was through a push for harmonisation measures, or an emphasis on institutional mechanisms of cooperation between the national competent authorities, the Member State evaluations of medicinal products still differed considerably.²⁴⁰ Majone has observed that “[t]he system lacked credibility, and was held responsible for the loss of international competitiveness by the European pharmaceutical industry.”²⁴¹ After a long period of discussions, the Council finally approved, in 1993, three pieces of legislation that would substantially transform the EU regulatory regime for pharmaceuticals.²⁴² The core of the reforms consisted in the establishment of two new procedures for medicines authorisation: the Centralised Procedure (C.P.) – which would be supported by a new European Agency for the Evaluation of Medicinal Products (EMA) – and the Decentralised and Mutual Recognition procedures.

The Centralised Procedure

Initially, the centralised procedure was mandatory for biotechnological products (Part A medicines) and optional for medicines which involved significant innovation, as well as for new drugs derived from human blood or human plasma (Part B medicines).²⁴³ For medicines falling under Part B of the Annex to the Regulation companies could therefore choose whether they wished to pursue a centralised application for a marketing authorisation or instead preferred the mutual recognition route. Under the centralised procedure pharmaceutical companies send an application for a European-wide marketing authorisation directly to the EMA. The Agency carries out a scientific assessment of the

²³⁷ *Ibidem*

²³⁸ European Commission, Report from the Commission on the Activities of the Committee for Proprietary Medicinal Products, COM (91) 39 Final, Brussels, 15 February 1991, p. 3

²³⁹ Council Directive 87/22/EEC, *OJ L 15*, 17.1.1987, p. 38–41, see Article 2(2)

²⁴⁰ *Supra* 226, [Feick], p. 12

²⁴¹ G. Majone, *The Credibility Crisis of Community Regulation*, *Journal of Common Market Studies*, Vol. 38, Issue 2, 2000, p. 280

²⁴² The three legislative documents are the following: 1) Council Regulation (EEC) No 2309/93, *OJ L 214*, 24.8.1993, p. 1–21; 2) Council Directive 93/39/EEC, *OJ L 214*, 24.8.1993, p. 22–30; and 3) Council Directive 93/41/EEC, *OJ L 214*, 24.8.1993, p. 40–40

²⁴³ See Annex to Council Regulation (EEC) No 2309/93 for distinction between Part A and Part B pharmaceuticals. As this chapter explains in more detail below, the scope of this procedure was extended in 2004 and it is now also mandatory for certain classes of medicines with a ‘new active substance’ and optional for those which are considered to have a significant ‘therapeutic value’

medicine – in which it examines its safety, quality and effectiveness of the medicinal product in question – and makes a recommendation to the European Commission (which has the final say in the authorisation process).²⁴⁴

The Decentralised and Mutual Recognition Procedures

Regardless of its significance, the centralised procedure is only one of the procedures through which medicines may be authorised in the European Union. Companies which hold a marketing authorisation in one Member State may wish to seek recognition of that original licence in one or more Member States (Mutual Recognition Procedure).²⁴⁵ The decentralised procedure, which is usually considered together with mutual recognition, differs from the latter in that it is applicable to medicinal products which have not received a marketing authorisation at the time of the application.²⁴⁶ In both of these procedures the evaluation of the medicine is carried out by the Reference Member State (where the drug was first authorised or the marketing application initially submitted), but the Concerned Member State (where another authorisation is sought) can object on public health grounds.²⁴⁷ If the Member States involved are not able to reach an agreement the matter is subjected to arbitration, where similarly to what happens in the centralised procedure, the CHMP, the Commission the Standing Committee become involved. The conclusions of the arbitration process are binding for the Member States.

National authorisation procedures

Pharmaceutical companies may simply wish to market a medicinal product within the territory of a Member State. In that case, the national authorisation procedures will apply. This option is only foreclosed if the product falls under the mandatory scope of the centralised procedure, in which case an application has to be sent to the EMA. The 1995 reforms have therefore resulted in what Feick calls a “remarkable range of three alternative regulatory routes” for medicines authorisation in Europe.²⁴⁸ As the author himself explains, this variety of options reflects different underlying market interests. The centralised procedure appears to be particularly of use for global and research-based pharmaceutical companies, which are ready to face strict measures of regulatory control and are best served by an authorisation process which reduces transaction costs and provides access to a wider market.²⁴⁹ On the other hand, the decentralised or national procedures may be more appropriate for companies which focus on more traditional products and target smaller, possibly only national, markets.

²⁴⁴ Regulation (EC) No 726/2004 of the European Parliament and of the Council, *OJ L 136, 30.4.2004, p. 1–33*, see Recital (19)

²⁴⁵ Council Directive 93/39/EEC, *OJ L 214, 24.8.1993, p. 22–30*, see Article 9

²⁴⁶ Directive 2004/27/EC of the European Parliament and of the Council, *OJ L 136, 30.4.2004, p. 34–57*

²⁴⁷ *Ibidem*, Article 10(1)

²⁴⁸ *Supra* 226, [Feick], p. 13

²⁴⁹ *Ibidem*, p.14

2- The 2004 pharmaceuticals review and the reform of the Centralised Procedure

In 2001 the Commission launched a review of the European legislation on pharmaceuticals.²⁵⁰ To that end, Enterprise Commissioner Erkki Liikanen and Health Commissioner David Byrne set up, in March of that same year, the “High Level Group on Innovation and Provision of Medicines” (or the G10 Medicines Group) to consider changes to the existing EU regulatory regime.²⁵¹ By May of 2002 the G10 Group had finished its final report, where a number of “recommendations for action” were presented.²⁵² The G10 Group emerged in a context where the loss of competitiveness of the European industry surfaced as a major theme. In a wide-ranging report submitted to the Directorate General for Enterprise of the European Commission in November of 2000, it is said that the “European industry has been losing competitiveness as compared to the USA [...]” and that “Europe is lagging behind in its ability to generate, organise, and sustain innovation processes that are increasingly expensive and organizationally complex.”²⁵³

Moved by the nature of this problem the European institutions began to reconsider the existing regulatory regime, namely in what concerns the balance between the centralised and decentralised procedures. Pharmacovigilance²⁵⁴ (post-authorisation supervision of medicines), an important pillar of the EU regulatory system, was affected by the reforms, namely to ensure further centralisation and clarification of reporting duties and institutional responsibilities.²⁵⁵ In another report carried out for the Commission, it was concluded that while “[t]he centralised and decentralised procedures are both perceived to have contributed in a qualitative and quantitative sense to the creation of a harmonised Community market in medicinal products”, there exists “criticism of particular aspects of both systems and in the case of the decentralised system, a level of real concern about the willingness of regulatory

²⁵⁰ See: <http://ec.europa.eu/enterprise/pharmaceuticals/review/index.htm>

²⁵¹ High Level Group on Innovation and Provision of Medicines, Final Report, 7 May 2002. See: <http://ec.europa.eu/enterprise/phabiocom/docs/g10-medicines.pdf>

²⁵² *Ibidem*

²⁵³ Alfonso Gambardella, Luigi Orsenigo and Fabio Pammoli, *Global Competitiveness in the Pharmaceuticals- A European Perspective*, Report Prepared for the Directorate General Enterprise of the European Commission, November 2000

²⁵⁴ The Commission has defined pharmacovigilance as: “(...) the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of medicinal products”. See: proposal for the Directive 2001/83/EC on the Community code relating to medicinal products for human use, Explanatory Memorandum, p. 4

²⁵⁵ The new legislation created an obligation on pharmaceutical companies to report, within 15 days, any serious adverse reactions to the Member States within the territory of which the incident occurred. Similarly, Member States were given a period of 15 days to communicate all suspected adverse reactions to the Agency. Thirdly, the new system laid down a duty on marketing authorisation holders to maintain detailed records of reported adverse reactions. An important step in the centralisation of the pharmacovigilance activities was the establishment of Eudravigilance, a central European database to which all adverse reactions are to be reported. Eudravigilance is meant to promote: 1) the electronic exchange of suspected adverse reaction reports between the EMA, National Competent Authorities and marketing authorisation holders, 2) the early detection of possible safety signals of medicinal products; and 3) the ongoing monitoring of potential safety issues in relation to reported adverse reactions

authorities to operate the central principle of mutual recognition.”²⁵⁶ In what the centralised process was concerned, this study concluded that that it was “capable of working very well” and emphasised a “high level of satisfaction with it”.²⁵⁷ It also stressed that many companies wished the procedure to become available to a wider class of products.²⁵⁸

Widening the scope of the centralised procedure

While the European system for medicines licensing has been based on a balance between the centralised and decentralised procedures, the amount of applications to centralised marketing authorisations falls clearly below the numbers of mutual recognition. From 1995 to 2000 inclusive, the EMA received 279 applications for a centralised authorisation. During the same period, a total of 988 procedures were finalised under the decentralised process.²⁵⁹ In 2004 the ambition of the Commission was, first, to extend the mandatory list of pharmaceutical products subject to the centralised procedure to all medicines containing a ‘new active substance’.²⁶⁰ This would mean that any product containing a substance which had not been previously authorised in the Community would necessarily be channelled through the centralised procedure. The argument was that the “decentralised procedure is not adequate for authorisation of medicinal products containing new active substances, taking into consideration the high costs for their development as well as the effects on society when those products are only placed on the market of a limited number of Member States.”²⁶¹

The increased reach which the Commission sought for the centralised procedure would find opposition in the Council, however. Some Member States argued that if the centralised procedure was already optional for such classes of products it would be unnecessary to make it obligatory.²⁶² This argument seems to be well grounded on the evidence available at the time. A report from the Commission notices that for “medicinal products containing new active substances and taking into account only those for which the centralised procedure is optional, since 1995 until 2000, 113 applications were made through the centralised procedure and 73 through the mutual recognition procedure.”²⁶³ In the end a compromise was reached whereby the mandatory list of the centralised procedure was extended to orphan medicinal products (medicines for rare diseases) and to those

²⁵⁶ Report on the "Evaluation of the operation of Community procedures for the authorisation of medicinal products", carried out on behalf of the European Commission by Cameron McKenna and Andersen Consulting, November 2000, p. 12

²⁵⁷ *Ibidem*, p. 13

²⁵⁸ *Ibidem*

²⁵⁹ Report from the Commission on the experience acquired as a result of the operation of the procedures for granting marketing authorisations for medicinal products laid down in Regulation (EEC) N° 2309/93, in chapter III of Directive 75/319/EEC and chapter IV of Directive 81/851/EEC. - COM/2001/0606 final, Brussels, 2001, p. 8-9

²⁶⁰ A ‘new active substance’ is one which on the date of entry into force of EC Regulation 726/2004 was not authorised in the Union

²⁶¹ *Supra* 256, [Cameron McKenna and Andersen Consulting], p. 13

²⁶² [Interview]: Respondent 1b (European Commission)

²⁶³ *Supra* 256, [Cameron McKenna and Andersen Consulting], p. 9

containing new active substances for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorder or diabetes.²⁶⁴ This list of diseases was not random. In 2004, for example, the therapeutic areas which met a higher number of positive opinions from the agency were: neurology and central nervous system (at 21.9%); and, secondly, immunotherapy and oncology, alimentary tract, and blood (all at 15.6).²⁶⁵

In addition to the widening of this mandatory list, the Commission also pushed for the extension of the centralised procedure as an optional authorisation route. Insisting that the decentralised process was not appropriate for certain classes of products, the Commission considered that the existing list B of the Annex was “inadequate and rather narrow, especially in the case of other innovative products and of generic medicinal products.”²⁶⁶ In the end, the 2004 Regulation would indeed open up the centralised procedure, as an optional authorisation procedure, for medicines which can be considered to be “therapeutically innovative”.²⁶⁷ In addition, even for products which are not particularly innovative, where a “benefit to society or to patients” can be found, access to this centralised route should be given.²⁶⁸ This would be the case, for example, with certain products which can be supplied without a medical prescription. Finally, the centralised process would also be available to generics of medicines authorised by the EU.²⁶⁹ These changes were significant because they had the potential to transform the relationship between the centralised procedure and innovation. If the centralised process was, before 2004, confined to biotechnology and particularly innovative products, applicants could now seek authorisation of medicines in which R&D was not so important, such as OTC (over-the-counter) products and generics. As this chapter explains below, however, the extent to which the centralised procedure has been used for the authorisation of such categories of products is not impressive.

Decentralised procedure: strengthened coordination and ‘European’ arbitration

The decentralised procedure, while considered to be of significant importance for medicines which do not bring impressive therapeutic advances and for products which target relatively small markets, continued to cause concerns in terms of its operation. Member State assessments often diverged and applicant companies usually decided to withdraw their applications once complications began to emerge.²⁷⁰ Because of this, the EU legislator decided, first, to foster the mechanisms of cooperation by formalising the work of the Coordination Group for Mutual Recognition and Decentralised Procedures (CMD (h)), which integrates members of the national competent authorities.²⁷¹ If conflicts

²⁶⁴ Supra 244, [Regulation (EC) No 726/2004], see Recital (8)

²⁶⁵ Supra 259, [Commission Report - COM/2001/0606 final], p. 30

²⁶⁶ Supra 256, [Cameron McKenna and Andersen Consulting], p. 13

²⁶⁷ Supra 244, [Regulation (EC) No 726/2004], see Recital (9)

²⁶⁸ *Ibidem*

²⁶⁹ *Ibidem*

²⁷⁰ Supra 256, [Cameron McKenna and Andersen Consulting], p.15-17

²⁷¹ See online (CMD h): <http://www.hma.eu/28.html>

cannot be solved in the CMD(h), the matter should be referred to arbitration in the CHMP. After the final opinion of the CHMP on the application, the Commission issues a decision instructing Member States either to grant, maintain, suspend, or withdraw/ revoke the marketing authorisation.²⁷² The results of this new regime have been mixed. The percentage of mutual recognition procedure applications which were referred to the CMD(h) has stabilised at 10%.²⁷³ With 81 referral procedures concluded by the CMD(h) in 2008, the group managed to reach agreement for 77% of procedures.²⁷⁴ Out of the 15 applications which were referred to the CHMP for arbitration, only four received a positive opinion from the Committee.²⁷⁵ More problematic though, withdrawals from the decentralised procedures continue to represent a major risk to their operation, as applicants often fear the discussion of objections at the CHMP level.²⁷⁶

3 - The mitigated impact of the 2004 reforms

The analysis of how the extended centralised procedure has worked in practice provides valuable insights into the nature of this authorisation process. Following the 2004 review there was an increase in the use of the centralised procedure. After a decline in applications in the year of 2005, which was attributed to global industrial factors, the 41 centralised applications of 2004 had gone up to 78 by 2006²⁷⁷ and to 90 by 2007.²⁷⁸ The EMA now talks about reaching the symbolic 100 mark of total approval requests in a period of one year. This growing use of the centralised process did not begin after 2004, however. Between 2002 and 2004 the number of applications for a centralised authorisation went from 31 to 51. The level of increase in applications following the 2004 extension of the centralised procedure does not seem to be too different from the evolution which took place in the years before the reforms came to effect. Two sets of factors help explain why the reform of the centralised procedure has had a limited effect on the number of applications. The first relates to the mandatory scope of the centralised procedure and the second touches on its optional segment.

To begin with, the extension of the mandatory list of the centralised procedure to cover new active substances aimed at the treatment of certain diseases has had no substantial effect in the relative weight that those products have in the overall numbers of this authorisation procedure. In 2004, the products containing a new active substance represented 88.2% of all new applications for a marketing authorisation²⁷⁹ and, two years later, that percentage remained at the same level (88.4%).²⁸⁰ In 2007

²⁷² European Commission, Volume 2A - Procedures for Marketing Authorisation, Chapter 3 – Community Referral Procedures. Brussels, September 2007, p. 17

²⁷³ CMD(h) summary of activities 2008, Ref: CMDh/011/2009, January 2009, p. 5

²⁷⁴ *Ibidem*

²⁷⁵ European Medicines Agency, Annual report (2008), EMEA/330566/2009, London, 2009

²⁷⁶ CMD(h), Summary of Activities in 2009, Doc. Ref.: CMDh/159/2010, January 2010, p. 8

²⁷⁷ European Medicines Agency, Annual report (2006), EMEA/MB/24167/2007/EN/FINAL, London, 2007, p. 23

²⁷⁸ European Medicines Agency, Annual Report (2007), Doc. ref.: EMEA/MB/17464/2008, London, 2008, p. 19

²⁷⁹ European Medicines Agency, Tenth Annual Report (2004), EMEA/61492/2005/EN/Final, London, 2005, p. 29

²⁸⁰ *Supra* 277, [EMA Annual Report 2006], p. 23

it actually came down to 62%.²⁸¹ While recommending a careful observation (since they show percentages and not absolute numbers), these figures suggest that the wider scope of the mandatory centralised procedure has not been responsible for any substantial increase in the use of this authorisation route. This is not altogether surprising, since the pre-2004 centralised regime already allowed for sufficient flexibility, in its optional segment, to include significantly innovative products (as will normally be the case with medicines containing a 'new active substance').²⁸²

In order to understand the mitigated impact of the 2004 extension of the centralised procedure one should also consider developments in what concerns the classes of medicines falling under the new optional centralised process. If before 2004 the centralised procedure was restricted to biotechnology or products involving significant innovation, following this reform the centralised procedure became open to other classes of products, such as OTC medicines and generics. Since 2006, it is indeed possible to observe an increase in the use of the centralised procedure by biosimilar medicinal products, as well as generics. The number of applications for these medicines, however, is still very low compared to those represented by new active substances. In 2006 there were 69 applications for products containing a new substance, a total of 9 applications for generics or hybrid products, and only 4 for biosimilar medicinal products.²⁸³ In the subsequent year, a higher number of initial EMA evaluations were taking place for biosimilars (10 applications); at the same time that the numbers for generics remained at the same level (also with 10 applications in 2007).²⁸⁴ Still, these numbers are not particularly impressive when compared to a total of 56 evaluations by the EMA for medicines with a new active substance, in that same year.²⁸⁵

The situation is quite different in the mutual recognition/decentralised procedures, where the significance of generics and OTC medicines has been acknowledged by the respective European associations. The European Generic Medicines Association (EGA) took good note of the fact that, in

²⁸¹ *Ibidem*, p. 19

²⁸² These conclusions are also supported by evidence on the therapeutic areas being covered in the centralised procedure applications. In 2003, the majority of the agency's evaluations for a marketing authorisation were taking place in immunotherapy and oncology (27%), neurology (24%) and anti-infectives/immunologicals (18%). These numbers are strikingly similar to those found in the post-reform period. In 2007, oncology is still first therapeutic area in terms of applications (at 26%), followed by neurology (17%) and anti-infectives (16%). See Annual Reports for 2003 and 2007 (cited above). For the 2003 report, see: European Medicines Agency, Ninth Annual Report (2003), London, 2004, p. 17

²⁸³ *Supra* 277, [Annual Report 2006], p. 23

²⁸⁴ *Supra* 278, [Annual Report 2007], p. 19

²⁸⁵ *Ibidem*. For the sake of clarification, it should nevertheless be noted that while truly innovative medicines (if not derived from biotechnology) will usually contain a new active substance (NAS), not all of these NAS will appear in products which bring significant innovation. An EMA official explains that until the end of 2008 the new active substances category has also included the so-called "fixed dose combinations" (a combination of two or more active substances which have previously been authorised in the EC). Therefore, between February 2005 and January 2009, out of a total of 117 new active substances there were about 20 fixed dose combinations. These developments deserve two comments. First, the numbers show that despite this flexibility the core of the optional CP has remained of use mainly for 'real' new active substances. Secondly, the exclusion, in January of 2009, of these fixed dose combinations from the optional segment of the centralised procedure only reinforces the link between this authorisation procedure and innovation in the pharmaceutical markets

2006, generic medicines represented almost 75% of all new applications finalised following the mutual recognition procedure.²⁸⁶ In what concerns OTC products, the Association of the European Self-Medication Industry is essentially concerned about the workings of the mutual recognition/decentralised procedures, which are considered to be “an important option” for manufacturers of non-prescription medicines.²⁸⁷

The link between the centralised procedure and R&D and innovation should also be understood in a context where influential stakeholders emphasise the existence of “considerable unmet medical needs” and the role that institutions play in the development of a new research agenda.²⁸⁸ While emphasising its determination to exploit and expand the science base of the EU, the European pharmaceutical industry likes to underline the importance of networks such as the Innovative Medicines Initiative (IMI), which is a public-private relationship established to reinvigorate the European biopharmaceutical sector.²⁸⁹ In a response to a 2007 Commission consultation paper, the Association of the British Pharmaceutical Industry (ABPI) considers that the ability of the EU regulatory framework to accommodate emerging technology is “the most challenging question which the Commission wishes to address.”²⁹⁰ Despite the scientific progress being slower than initially anticipated, the ABPI expects a “revolution” which will lead to regenerative therapies, personalised medicinal products, nanomedicines and other “therapeutic breakthroughs”.²⁹¹

While the development of such challenges is beyond the scope of this chapter, suffice is to say that scientific progress is likely to have fundamental implications for existing regulatory structures. Furthermore, even for the time being, these reminders of the industry have an eye in the current framework for medicines regulation in Europe. The European Federation of Pharmaceutical Industries and Associations (EFPIA) notes that emerging technologies call for a renewed emphasis on issues such as the “provision of development advice” and demand an increased “centralisation of regulatory activities.”²⁹² The role of the centralised procedure in responding to scientific progress, as well as that of the EMA in supporting a novel and more engaged dialogue with the industry, surface as major themes in the emerging context of pharmaceuticals regulation.

²⁸⁶ Response by the European Generic Medicines Association to the 2007 Commission consultation paper: “The Future of Pharmaceuticals for Human Use”, October 2007, p. 3

²⁸⁷ Response of the Association of the European Self-Medication Industry to the 2007 Commission consultation paper “The Future of Pharmaceuticals for Human Use”, October 2007, p. 4

²⁸⁸ Response of the European Federation of Pharmaceutical Industries and Associations to the 2007 Commission consultation paper “The Future of Pharmaceuticals for Human Use”, October 2007, p. 16

²⁸⁹ The Innovative Medicines Initiative (IMI), see online at: http://imi.europa.eu/index_en.html

²⁹⁰ An outline/draft of the contribution of the Association of the British Pharmaceutical Industry to the 2007 Commission consultation paper “The Future of Pharmaceuticals for Human Use”, October 2007, p. 7

²⁹¹ *Ibidem*

²⁹² *Supra* 288, [Response EFPIA 2007], p.16-17

4- Formal architecture of the centralised procedure and ‘new active substances’

The centralised procedure can be broadly divided into two stages: the scientific evaluation and the administrative decision-making process. The EMA has been entrusted with the first task. Within the Agency, it is the CHMP (Committee for Medicinal Products for Human Use) which performs the scientific assessment of medicines for human use. This Committee consists of one member appointed by each of the EU Member States and also includes members appointed by each of the EEA-EFTA States.²⁹³ In addition, the Committee may “in order to complement its expertise” appoint up to five co-opted members on the basis of their specific scientific competence.²⁹⁴ The scientific assessment of an application for a marketing authorisation is performed by a Rapporteur, which is selected from amongst the members of the CHMP. Where appropriate, the Rapporteur may be supported by a Co-Rapporteur.²⁹⁵ Following a scientific discussion in the CHMP (developed below), the Committee adopts an opinion on whether the medicinal product should be authorised. Where possible this should be done by consensus, but absolute majority voting may be used.²⁹⁶ In case the opinion of the CHMP is in support of giving a marketing authorisation, that recommendation shall be sent to the European Commission. Once the Commission has in its power the opinion of the CHMP it has 15 days to prepare a draft decision. The draft Commission measures should then be sent to the Standing Committee on Medicinal Products for Human Use, where the Member States are represented.

By considering the approval of two medicines evaluated under the centralised procedure (Acomplia and Champix), this chapter will examine how these procedures have worked in practice. Acomplia, which contains the active substance rimonabant, is used together with diet and exercise to treat obese and overweight patients who also have other risk factors, namely type 2 diabetes or dyslipidaemia (excessive levels of fat in the blood).²⁹⁷ This medicine was authorised in the European Union in June 2006 and was marketed in 18 EU countries. At the time this product was assessed by the EMA, the CHMP was aware that Acomplia could involve psychiatric side effects, in particular depression, but still concluded that it was effective “in weight reduction in obese or overweight patients with associated risk factors” and that its benefits outweighed existing concerns. New data on psychiatric side effects which became available after its authorisation led the CHMP to restrict the

²⁹³ The European Medicines Agency (EMA), Committee for Medicinal Products for Human Use – Rules of Procedure, EMEA/45110/2007; EMEA/MB/87146/2007, Article 1

²⁹⁴ *Ibidem*, Article 1 (3)

²⁹⁵ *Ibidem*, Article 6

²⁹⁶ European Commission: Enterprise and Industry Directorate General - Notice to applicants, Volume 2A, Procedures for Marketing Authorisation, Chapter 4, Centralised Procedure (April 2006), p. 30.

²⁹⁷ The active substance of Acomplia, rimonabant “is a cannabinoid receptor antagonist. It acts by blocking a specific type of receptor, the cannabinoid type 1 (CB1) receptors. These receptors are found in the nervous system, and they are part of the system the body uses to control food intake.” European Public Assessment Report (EPAR) for Acomplia, Summary for the Public, EMEA/H/C/666, p. 1

medicine's use in July 2007.²⁹⁸ In May of 2008 the Committee again updated the product information of Acomplia, advising doctors to monitor patients for signs of psychiatric disorders. Since new data was confirming these concerns, the CHMP decided to ask a group of experts to review this medicinal product. The group met in June 2008, concluding that the benefit/risk balance had "narrowed" since the approval of Acomplia, but still noted that more data was needed for a more conclusive position to be taken.²⁹⁹ Because the latest data provided by the company had increased existing fears, the European Commission issued a formal request under Article 20 of Regulation (EC) 726/2004, which allowed the CHMP to prepare an opinion on what regulatory action to be taken - maintain product on market, change product information, suspension or withdrawal from market? The CHMP considered that Acomplia was "moderately effective in helping patients to lose weight", but also noted that the "risk of psychiatric side effects, including depression, sleep disorders, anxiety and aggression is approximately doubled in patients taking Acomplia, compared to obese or overweight patients taking placebo (a dummy treatment)".³⁰⁰ It was also noted by the Committee that there had been reports of serious psychiatric disorders, including suicide. All this led the CHMP, in October 2008, to conclude that the benefits of the medicine no longer outweighed its risks and to recommend the suspension of the marketing authorisation of Acomplia.

The second case-study, Champix, is a medicine which contains the active substance varenicline and which is used by patients to help them stop smoking.³⁰¹ The applicant Pfizer Limited submitted its application in November 2005 and in July of the following year the CHMP concluded that in the light of the data submitted and the scientific discussion that had taken place, a positive opinion should be granted for the marketing of Champix. It was considered that the medicine had shown effectiveness in helping patients stop smoking and that its risks did not outweigh the benefits. The marketing of Champix has raised concerns about the product's safety. In December 2007 the EMA concluded that it was necessary to provide updated warnings to doctors and patients, in order to "increase awareness of cases of suicidal ideation and suicide attempts reported in patients using Champix (varenicline)".³⁰² Despite these concerns, Champix is still marketed across the European Union. Champix and Acomplia are significant medicines both for their alleged therapeutic value and because of the intense institutional history which they have been associated with. These products integrate

²⁹⁸ European Medicines Agency, 'Questions and answers on the recommendation to suspend the marketing authorisation of Acomplia (rimonabant)', EMEA/537153/2008, London, 2008

²⁹⁹ *Ibidem*

³⁰⁰ *Ibidem*

³⁰¹ The European Public Assessment Report of Champix (Summary for the Public - EMEA/H/C/699) explains that: "People who smoke become addicted to nicotine, a chemical in tobacco. Nicotine acts in the nervous system, where it binds to receptors and triggers the release of a chemical messenger, dopamine, which plays a part in the pleasure derived from smoking. The active substance in CHAMPIX, varenicline, can bind to some of these receptors, the $\alpha 4\beta 2$ nicotinic acetylcholine receptors. When binding to these receptors, varenicline acts in two ways: it acts like nicotine (partial agonist) and this helps to relieve craving symptoms, but it also acts against nicotine (antagonist), by taking its place, and this helps to reduce the pleasurable effects of smoking."

³⁰² European Medicines Agency, Press Release: 'European Medicines Agency concludes new advice to doctors and patients for Champix needed', doc: EMEA/595516/2007, London, 2007

emerging therapeutic areas (anti-smoking and anti-obesity, respectively) and therefore provide good examples of the new risks facing the centralised procedure evaluations. In addition, institutional patterns in the assessment of these products after post-authorisation complications started to occur is something which this chapter is also interested in exploring. The next section considers what the scientific assessment of these two products can tell us about the role of the Rapporteurs in the centralised procedure.

5- The reliance on the Rapporteur and regulatory capacities

Once a successful centralised procedure application enters the primary evaluation stage, the product has already been allocated a Rapporteur and a Co-Rapporteur to perform its scientific assessment. This primary assessment stage can be divided into two distinct moments. First, the Rapporteur and Co-Rapporteur have 80 days to send their (separate) initial Assessment Reports to the CHMP.³⁰³ These reports assess the quality, efficacy and safety of the medicinal product. On the basis of those criteria, the reports include a recommendation to the CHMP as to whether a marketing authorisation should be granted. Secondly, the CHMP is given a period of 20 days to submit its comments and another 20 days to adopt a formal position, a provisional recommendation and a list of questions to be addressed by the applicant company. After day 120, the clock stops for this primary evaluation stage.³⁰⁴ The applicant then has 3 months to answer the CHMP questions, although this time limit can be extended up to 6 months if necessary.³⁰⁵ Once those answers are received, a secondary evaluation stage begins. The Rapporteur and the Co-Rapporteur have 30 days to present a Joint Assessment Report which addresses the replies submitted by the company to the CHMP's list of questions. Following this, the CHMP has 20 days to comment on the Joint Assessment Report. If no outstanding issues remain, the Committee shall adopt an opinion within 10 days. On the other hand, the CHMP may decide, also within 10 days, that outstanding issues need to be addressed, which would require a hearing.³⁰⁶ If that is the case, the clock stops at day 180. Once the hearing has taken place, the CHMP is given 30 days to adopt a final opinion on the matter, meaning that day 210 is the legal deadline for centralised authorisations. Notwithstanding this limit, since 2005 it is possible to see a decrease in the active time of the centralised procedure evaluations. After an average active time of 194 days in 2004, the assessment procedures have been quicker in recent years (189 days in 2005; 176 in 2006; and 183 in 2007).³⁰⁷

³⁰³ Supra 296, [Commission Notice to applicants -Procedures for Marketing Authorisation], p. 25-26

³⁰⁴ *Ibidem*

³⁰⁵ *Ibidem*

³⁰⁶ *Ibidem*

³⁰⁷ These numbers only include positive CHMP opinions. See: European Medicines Agency, 'Survey 2007 on the performance of EMEA scientific procedures for medicinal products for human use', Management Board, March 2008, Doc. Ref.

EMEA/158877/2008, p. 4

The Rapporteur and the lack of a European regulatory capacity

One of the main features of this scientific assessment process is the reliance on a Rapporteur and a Co-Rapporteur to pursue the initial evaluation of the medicinal product seeking a marketing authorisation. The appointment of the Rapporteurs should be initiated at the CHMP meeting following the receipt of the company's letter of intention to submit a centralised procedure application.³⁰⁸ Both the Rapporteur and Co-Rapporteur are appointed from amongst the members of the CHMP. The appointment is said to be based on "objective criteria", namely to "allow the use of the best and available expertise" on the relevant scientific area.³⁰⁹ In order to pursue the scientific evaluation of the product, the Rapporteur and Co-Rapporteur may choose, on the basis of a database of European experts, the members who will integrate their assessment teams.³¹⁰ This list includes experts who have been put at the disposal of the EMA by the Member States or which the Agency has directly appointed.³¹¹

The mission of the Rapporteur in the scientific evaluations draws attention to the lack of a European regulatory capacity. Indeed, the position of Rapporteur both reflects and operationalizes the Agency's networking model. The necessary scientific work for the assessment of a product does not take place in London, where the EMA is located, but in the offices of the National Competent Authority of the Member State from which the Rapporteur comes from. This is explained by an EMA scientific administrator, who observes that the scientific evaluations "take place at the national level" and that the EMA staff is not there to "re-do" this work.³¹² Such reliance on the NCAs is not a surprise considering the very limited scientific resources of the Agency's Secretariat. Presently, the EMA has a total of 226 members which are designated as 'scientific administrators', a category which essentially includes physicians, pharmacists and biologists.³¹³ While the Secretariat (which has been given a scientific mandate since 2004) is now performing the initial scientific assessments in the field of orphan and paediatric drugs,³¹⁴ outside these areas it has a marginal role in the preparation of CHMP opinions. Its mission is mainly devoted to the administrative handling of centralised procedure evaluations.

The relationship between the Rapporteur and applicant companies

It has been mentioned above that the importance of new and innovative medicines in the centralised procedure places the EMA in a challenging institutional context. As these products do not have a regulatory history; there is no 'real-life' experience with the marketing of the substance to which the

³⁰⁸ Supra 296, [Commission Notice to applicants -Procedures for Marketing Authorisation], p.12

³⁰⁹ *Ibidem*

³¹⁰ *Ibidem*, p. 13

³¹¹ *Ibidem*

³¹² [Interview]: Respondent 2b (EMA)

³¹³ *Ibidem*

³¹⁴ [Interview]: Respondent 3b (EMA)

regulator can turn to understand its benefit/risk balance more fully. This puts the pharmaceutical firm, which developed the product and produced its application dossier, in a strong position.

Moreover, the contacts between the Agency and the pharmaceutical companies begin several months before an application for a centralised authorisation is formalised. According to a Commission “Notice to Applicants”, firms should notify the Agency of their intention to submit an application for a centralised procedure authorisation with an anticipation of at least seven months.³¹⁵ During this pre-submission stage, the meetings between the Rapporteurs and the applicant companies may be of considerable importance and are said to take place on an “extremely common” basis.³¹⁶ Information on these exchanges is very difficult (or even impossible) to find because there are no formal records and they do not take place in London, but in the offices of the National Regulatory Authority from which the Rapporteur comes from.³¹⁷ It is also worth mentioning that not all the Rapporteurs feel the same way about these pre-submission meetings. Some of them are said to be “very reluctant” to see the applicant at this stage “because they understand that this may interfere with the [assessment] procedures.”³¹⁸ These meetings represent the underworld of the EMA and the centralised procedure; the less than visible dimension of its scientific assessment processes, where national regulatory authorities (Rapporteurs) are allowed to disregard the Agency’s commitments to openness and accountability.

After an application is formally submitted and if clarification regarding the data submitted is considered necessary, the applicant company and the Rapporteur (and Co-Rapporteur) may also liaise, in which case they shall inform the product team leader (official from the EMA secretariat) of the outcome of their discussions.³¹⁹ These meetings take place in the London headquarters of the Agency, they are recorded, and the product team leader is also present. This dialogue is particularly important after the CHMP has adopted a list of questions to be addressed by the applicant. Clarification meetings may be convened between the latter and the Rapporteurs, so as to provide an “opportunity for clarification and transparent guidance on the list of questions and proposed strategy

³¹⁵ Supra 296, [Commission Notice to applicants -Procedures for Marketing Authorisation], p. 10. In addition, the increased importance attached to scientific advice from the EMA to the companies reinforces this liaison at the pre-submission stage. The EMA management notes that the numbers of successful applications for a centralised procedure authorisation show an “association between prior scientific advice and success of MAAs [marketing authorisations applications].” This study interestingly concludes that out of 236 applications submitted since 2001, the “probability of a negative outcome (negative opinion or withdrawal) was 19% (13/68) for applications with CHMP scientific advice compared to 28% (47/168) for applications without scientific advice.” See: European Medicines Agency, Survey 2006 on the performance of EMA scientific procedures on medicines for human use, Management Board, March 2007, EMEA/489472/2006, p. 10

³¹⁶ [Interview]: Respondent 4b (EMA)

³¹⁷ *Ibidem*

³¹⁸ *Ibidem*

³¹⁹ European Medicines Agency, ‘CHMP Rapporteur/Co-Rapporteur appointment: principles, objective criteria and methodology’, EMEA/124066/2005 Rev 2, London, 2006

for the responses (...)”³²⁰ These meetings are considered to be particularly important when the CHMP list of questions have identified “major concerns” in the assessment of the product.³²¹ During the Acomplia and Champix approval processes two clarification meetings between the Rapporteurs and the applicant companies took place for each of the products.³²² In the case of Acomplia, there was also a de-briefing meeting regarding a draft list of CHMP questions.³²³ These moments of coordination stress the importance of the conversations between the Rapporteurs and the applicant companies, highlight the peculiar mission of the Rapporteur, and finally draw attention to the ‘privileged’ information and knowledge of the product which this CHMP member benefits from and brings to the centralised procedure deliberative process.

The proximity between the Rapporteurs and the companies is further strengthened during the post-authorisation period. During the life-time of the product (a centralised marketing authorisation is valid for 5 years) the marketing authorisation holder may wish to alter or improve the product or the EMA may consider that changes need to be introduced to the marketing authorisation to reflect new information.³²⁴ For certain minor variations (Type I) and for all major variations (Type II), the (same) Rapporteur is involved. The troubled case of Acomplia provides a good example of how demanding this post-authorisation phase can be. Before being taken from the market, Acomplia suffered four Type II variations, of which two are especially relevant: an update to the summary of the product’s characteristics (SPC) in July 2007 “to reflect new contraindication in patients with ongoing major depression and/or ongoing antidepressive treatment”; and another update to the SPC to include a further warning related to depressive reactions, in May 2008.³²⁵

It can be concluded that while the existence of a Rapporteur seems to provide an efficient way of conducting the required scientific dialogue with the applicant, the nature of this proximate and enduring relationship may promote a sense of affinity within the process, which may have to be looked after.³²⁶ The question which follows is whether, and how, the discussions in the CHMP force the Rapporteurs to justify their positions (Assessment Reports) to the remaining members of the Committee and if these processes of internal accountability mitigate the risks identified here.

³²⁰ European Medicines Agency, Committee for Proprietary Medicinal Products (CPMP), Guidance on the Rapporteurs meetings with applicants on the CPMP list of questions. London, 2002, CPMP 2270/02, p. 2

³²¹ [Interview]: Respondent 4b (EMA)

³²² *Ibidem*

³²³ *Ibidem*

³²⁴ European Commission, Notice to applicants, Volume 2A Procedures for marketing authorisation, Chapter 5, Variations, Brussels, 2004, ENTR/F2/BL D(2001)

³²⁵ European Medicines Agency, ‘Procedural steps taken and scientific information after the authorisation - Acomplia’; this document is available online here: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/000666/WC500021286.pdf

³²⁶ J. Black, *New Institutionalism and Naturalism in Socio-Legal Analysis: Institutional Approaches to Regulatory Decision Making*, Law & Policy, Vol. 19, No. 1, 2007, p. 78

6- The CHMP and the nature of the deliberative process

After an initial scientific assessment stage based on a strong element of 'personalisation' (Rapporteur), the CHMP serves the important function of promoting a wider level of participation in the adoption of the Agency's recommendation. At this stage, therefore, the scientific debate becomes a 'European' one, not just an issue to be dealt with by the National Competent Authority of the CHMP member who was entrusted with the role of Rapporteur. Although all the Member States are represented in the CHMP, the operation of this committee has been quite asymmetric. A senior EMA official explains that discussions are essentially restricted to five Member States (United Kingdom, Germany, France, Sweden and The Netherlands).³²⁷ The position of Rapporteur (and Co-Rapporteur) is usually decided between these members of the Committee.³²⁸ Then there is, according to EMA officials, a "silenced majority" of members which merely observe the debates taking place.³²⁹ Outside the group of five leading Member States there are also differences, however. Denmark, for example, has a certain degree of intervention in areas where it possesses additional expertise.³³⁰ The level and type of participation also varies according to the accessibility of the issue under discussion. When an over-the-counter medicinal product is being assessed, for example, the debates often get livelier.³³¹ Again, this stresses the peculiarities of new active substances and the impact they have on the development of the processes of scientific evaluation. As these products demand more advanced science and regulatory expertise, CHMP discussions end up being restricted to a few Member States which can be 'trusted'. This means that number of national authorities which check the assessment reports of the Rapporteurs is much thinner than the wide composition of the Committee suggests.

The peer review system and its weaknesses

As part of its "Quality Assurance System", the EMA has established a process of peer review to check the quality and coherence of the assessment reports submitted to the CHMP by the Rapporteurs.³³² The peer reviewers are chosen from amongst the members of the CHMP. It is up to this committee to define the scope of the peer review as well as the number of reviewers to pursue this task (normally two members). Peer review only lasts for a period of 40 days. It begins when the Rapporteurs release their initial Assessment Reports (Day 80) and stops once the CHMP has adopted its first consolidated list of questions (Day 120).³³³ The review is therefore limited to the primary evaluation stage, which leaves, for example, the Rapporteurs' Joint Assessment Report outside the scope of this quality assurance mechanism.

³²⁷ [Interview]: Respondent 3b (EMA)

³²⁸ *Ibidem*

³²⁹ *Ibidem*

³³⁰ [Interview]: Respondent 5b (EMA)

³³¹ *Ibidem*

³³² Supra 296, [Commission Notice to applicants -Procedures for Marketing Authorisation], p. 12

³³³ *Ibidem*

A third dimension of peer review in the centralised procedure questions the level of controls it places on the assessment reports, the duties of justification which it requires from the Rapporteurs. In this regard, a senior EMA official notes that peer review normally involves “consensus views”.³³⁴ The cases of Acomplia and Champix are good examples of this, since for both products the two peer reviewers concurred with the Rapporteur and Co-Rapporteur’s recommendations. This is not to say, however, that the reviewers agreed with everything. In the evaluation of Champix (anti-smoking medicine), for example, one of the reviewers considered that there had been an important lack of data in terms of clinical safety since the company had not provided an interaction study with antidepressants.³³⁵ According to the review, this was problematic because “many persons who intend to stop smoking are currently treated by antidepressants.”³³⁶ Therefore, this reviewer concurred with the Rapporteurs on the conclusions and on the benefit/risk assessment, but disagreed on the product information section, arguing that the applicant “should be asked to develop an informational programme for both professionals and patients.”³³⁷

These reviews of the assessment reports essentially discuss the questions (or objections) to be addressed by the applicant. In this sense, they set the ground for the CHMP’s list of questions which the company should answer within three months. With Acomplia, both the Rapporteur and the Co-Rapporteur had considered that the psychiatric safety profile of rimonabant was a “major concern”.³³⁸ Still, as one of the reviewers noted, the two assessment reports “allow to conclude that provided the safety issues are adequately addressed, the benefit/risk in weight management could be acceptable.”³³⁹ When examining the Rapporteur’s major objection #6, one reviewer asks that this be formulated in a “more precise” way, as the “risk of psychiatric reactions and in particular depressive reactions represent a major problem associated with rimonabant (...)”.³⁴⁰ This restraint is illustrative of the type of worries which the peer reviewers had; rarely asking for more than a refinement to the questions or concerns expressed by the Rapporteurs.

This should not be understood as a scientific or technical criticism. Under conditions of uncertainty it is very difficult to always “get it right”. The point that can be made, though, is a procedural one. The peer reviews did not to show a capacity to destabilise the authority of the Rapporteurs in the centralised procedure; they generally failed to open up a new page in the assessment of the products on which the CHMP could perhaps build on. These peer review documents, in its worst, appear to be

³³⁴ [Interview]: Respondent 6b (EMA)

³³⁵ European Medicines Agency – ‘Peer Review of the Day-80 Assessment Reports for Champix (Varenicline tartrate)’ – EMEA/H/C/699, London 24 February, 2006, Doc. Ref. EMEA 49094/2006. See in particular: Annex 1 – Instructions and template for comments and peer review of the initial assessment reports, 22/02/2006, doc: SOP/H/3015, p.4-6

³³⁶ *Ibidem*

³³⁷ *Ibidem*

³³⁸ European Medicines Agency, ‘CHMP Peer Review Comments on Preliminary Reports – Acomplia’ (EMEA/H/C/666), 25th August 2005; [Document available upon request only]

³³⁹ *Ibidem*

³⁴⁰ *Ibidem*

a comparison between the two assessment reports (Rapporteur and Co-Rapporteur), failing to incorporate an autonomous scientific judgement on the products. The next section suggests that these limitations be understood in a wider context; one which links deliberation to the nature of the issues (products) subject to debate in the centralised procedure.

The CHMP and the checks on the Rapporteur

Consensus is increasingly dominant in CHMP deliberations. A 2006 EMA survey shows that out of 26 medicines that started to be reviewed in 2005 and which received a positive CHMP opinion, only one (Tandemact) was not approved “following consensus views in the Committee.”³⁴¹ The same study observes that in “previous years majority views have been more prevalent.”³⁴² Therefore, a total of 33 (10.5%) out of the 313 medicines approved between 1995 and 2006 were approved with divergences in the CHMP.³⁴³ The number of cases where CHMP recommendations are not approved by consensus has therefore been low.

It is suggested that these figures be understood in the context of the empowerment of the Rapporteurs. Beginning with Acomplia, the applicant company had proposed that this drug be approved for the management of multiple cardiovascular risk factors, weight management, type 2 diabetes, dyslipidemia, and smoking cessation and maintenance of abstinence.³⁴⁴ The two Rapporteurs - Dr. Salmonson (Swedish authority) and Dr. Zwieten-Boot (Dutch authority)– agreed that while “disturbing” concerns on the psychiatric safety of the product persisted, as long as the applicant provided adequate responses this medicine could be approved “for the indication as an adjunct treatment to diet and exercise to reduce weight in overweight patients (...), and in obese patients.”³⁴⁵ Their view was that “the occurrence of symptoms indicative of depressions is definitely not trivial” but could be addressed in the SPC.³⁴⁶ The efficacy of the product was considered to be “clinically relevant”, but it also did not provoke great enthusiasm.³⁴⁷ In terms of deliberation, the important point is that the other CHMP members did not oppose the Rapporteurs’ evaluation. Even with a medicine which was considered to have a very fragile risk benefit advantage, the agreement of the two Rapporteurs strongly influenced the Committee debates.

³⁴¹ European Medicines Agency, ‘Survey 2006 on the performance of EMEA scientific procedures for medicinal products for human use’, Management Board, 2007, p. 4

³⁴² *Ibidem*

³⁴³ *Ibidem*

³⁴⁴ European Medicines Agency: Committee for Human Medicines for Human Use: ‘Final Minutes, CHMP plenary meeting 23-26 January 2006’, London 24th February 2006, CHMP/42629/2006 Rev. 1

³⁴⁵ *Ibidem*

³⁴⁶ European Medicines Agency: Rapporteurs’ Day 150 Joint Response Assessment Report – Overview – Acomplia. EMEA/H/C/666, EMEA/H/C/691, 2nd January 2006, p. 33

³⁴⁷ *Ibidem*, p. 32

The CHMP discussions on Acomplia were more divisive in areas where the Rapporteurs diverged. Dr. Salmonson (Rapporteur) believed that, in addition to weight reduction, the product was also approvable for the specific indication of type 2 diabetes.³⁴⁸ On the other hand, several members of the committee supported a different line, following the Co-Rapporteur's position, which essentially argued that a bodyweight **independent** reduction of glucose (the level of sugar in the blood) "had not been convincingly demonstrated" [Emphasis original].³⁴⁹ An oral explanation by the applicant company was held in March 2006, where the type 2 diabetes indication was debated, as was the wording of the weight management indication.³⁵⁰ Following the company's presentation, the open of exchange views between the Committee members was as intense as it got in the evaluation of Acomplia. In the end, the position of the Co-Rapporteur won more support and the CHMP therefore concluded that an indication in type 2 diabetes "was not approvable".³⁵¹

The debates on anti-smoking medicine Champix show a similar institutional pattern. Both the Rapporteur and the Co-Rapporteur – Dr. Thirstrup (Danish authority) and Dr. Zwieten-Boot respectively (Dutch authority) – agreed that while certain issues had to be clarified by the applicant company, the product could be approvable for smoking cessation. The Committee supported this line in the first time it was called to evaluate Champix (20-23 March 2006); concluding that as long as the company responded satisfactorily to the list of questions the product could be approved for the above mentioned indication.³⁵² The agreement between the Rapporteur and the Co-Rapporteur made this possible. The following meetings, in June and July 2006, were devoted to a few methodological issues, namely the question of whether or not an additional 12 weeks treatment for quitters was necessary to improve long-term abstinence.³⁵³ On this issue, the Rapporteur was satisfied with the responses which the applicant firm had submitted. The Co-Rapporteur, however, stated that the population in need of a second 12 weeks course "was difficult to identify" and that it was not understandable why the applicant was being "inflexible" in terms of exploring who should be treated for an additional 12 weeks and who should not.³⁵⁴

This outstanding issue was addressed by the company during an oral explanation before the CHMP, on July 26th 2006. After the applicant had provided its responses, the Committee debated this issue, with Dr. Ljungberg (Swedish authority) arguing that the company "should have provided a better representation of the study results."³⁵⁵ These discussions led the Committee to introduce a wording

³⁴⁸ Supra 344, [CHMP plenary meeting 23-26 January 2006]

³⁴⁹ *Ibidem*

³⁵⁰ European Medicines Agency: 'Committee for Medicinal Products for Human Use: Final Minutes', CHMP plenary meeting 20-23 March 2006, London 27th April 2006, CHMP/119089/2006 Rev. 1

³⁵¹ *Ibidem*

³⁵² *Ibidem*

³⁵³ European Medicines Agency – Committee for Medicinal Products for Human Use: Final Minutes, CHMP plenary meeting 24-27 July 2006, London 19th September 2006, CHMP/299312/2006 Rev. 1

³⁵⁴ *Ibidem*

³⁵⁵ *Ibidem*

amendment to the SPC (summary of the product's characteristics) so as to reflect that longer treatment could be considered under certain circumstances.³⁵⁶ As it had happened in the approval of Acomplia, the Co-Rapporteur was able to win the support of most CHMP members for her position.

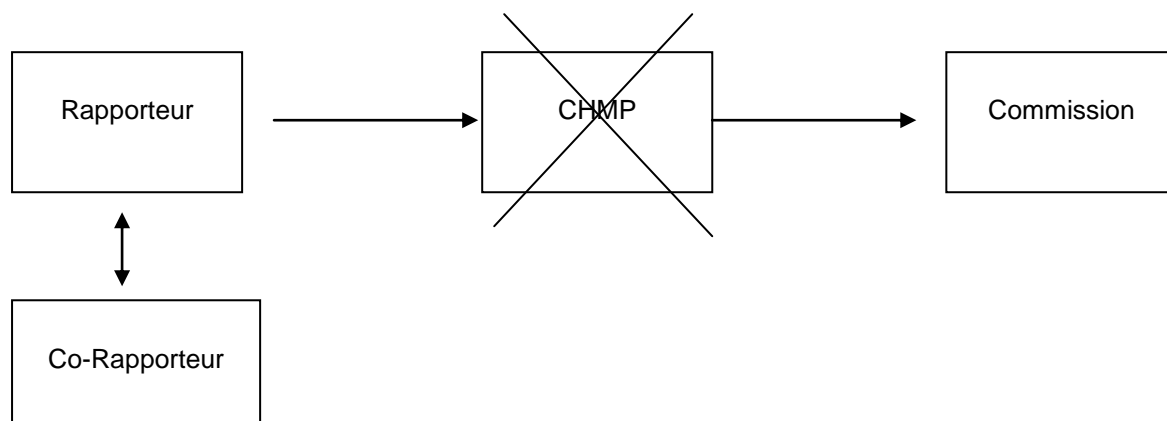


Figure 1: The dynamics of deliberation in the case of Champix and Acomplia: the agreement between the Rapporteur and the Co-Rapporteur meant that the role of the CHMP in the technical discussions was a very limited one.

A conclusion which can be taken from this evidence is that while the existence of a Co-Rapporteur (to perform a scientific evaluation of the product independently from the Rapporteur) seems to be a very powerful mechanism to check the Assessment Report of the Rapporteur; nothing seems to stifle debate and reduce contestation in the CHMP discussions as much as the concurrence between the two Rapporteurs. Where a disagreement exists, the Committee members are asked to consider which position is 'better', which creates the conditions for quite an intense exercise of deliberation. The authority of the assessment reports is (only) disrupted when the Rapporteur and the Co-Rapporteur diverge in their evaluations. The nature of new active substances helps explain why the initial scientific assessment is so crucial, since their evaluation takes place under conditions of uncertainty. It is important to distinguish these new substances from mere reproductions of other medicines (generics), as well as from products which introduce some changes to an active substance which has been previously authorised ('me-toos'). As scientific innovation can quite important in the development of new active substances and these have not been tested on the market, their evaluation is not only more difficult; it is also favours asymmetries of information because a full understanding of the issues requires resources, expertise and time. The CHMP procedures both confirm and accentuate this risk as only the Rapporteurs have complete access to the file ("dossier") of the medicinal product.³⁵⁷ The other members of the Committee have to limit themselves to the data contained in the assessment reports; a restriction which was criticised in the peer reviews of the Rapporteurs in the cases of Champix and Acomplia.

³⁵⁶ *Ibidem*

³⁵⁷ [Interview]: Respondent 6b (EMA)

The CHMP under conditions of 'crisis'

Finally, the contentious regulatory experience with the approval and later suspension of the marketing authorisation of Acomplia suggests that the occurrence of a 'crisis' with a product influences the CHMP discussions in important ways. Post-authorisation debates on the safety of Acomplia began to gain force in June 2007, after the (American) Food and Drug Administration (FDA) decided to recommend a negative opinion on a new marketing application for rimonabant (the active substance of Acomplia). The FDA concluded that there was a serious risk of psychiatric adverse reactions (e.g. depression, suicidal ideation and anxiety).³⁵⁸ Another important safety concern was related to the combined use of rimonabant with antidepressants. In its 16-19 July 2007 meeting, the CHMP decided, following the opinion of the Agency's Pharmacovigilance Working Party (PhVWP), to introduce SPC changes to reflect these safety issues.³⁵⁹

As the reporting of depressive disorders, aggressiveness and suicidality had increased since that period, the CHMP agreed, in April 2008, that it was necessary to reconsider the benefit/risk balance of Acomplia and for that purpose decided to request the opinion of the Agency's Scientific Advisory Group (SAG) for Diabetes/Endocrinology, which met in June 2008.³⁶⁰ It was the view of the experts that "whilst the product was considered effective, the Benefit risk margin had narrowed and the product might be inappropriate for non expert use."³⁶¹ In the CHMP July meeting the marketing authorisation holder (MAH) was requested to submit further analyses on the safety concerns. It was the Committee's view that the "overall assessment of these data confirmed the previous safety concerns of Acomplia without identifying any subgroups with a potentially more favourable benefit/risk balance."³⁶² Following this evaluation, the European Commission initiated a procedure under Article 20 of Regulation (EC) No 726/2004, requesting the CHMP to consider whether the product should be maintained, varied, suspended or withdrawn from the market. The marketing authorisation holder was called for an oral explanation before the Committee on October 20th 2008 and, following that presentation, a discussion was held on what line of action to take.³⁶³ A minority of the Committee members (5 out of 31) wished the product to be maintained on the market subject to more SPC changes. After some discussion it was agreed, by consensus, that the marketing authorisation of the product should be suspended (not revoked).³⁶⁴

³⁵⁸ European Medicines Agency – 'Committee for Medicinal Products for Human Use: Final Minutes', CHMP plenary meeting 16-19 July 2007, London 25th September 2007, CHMP/341960/2007 Rev. 1

³⁵⁹ *Ibidem*

³⁶⁰ European Medicines Agency – 'Committee for Medicinal Products for Human Use: Final Minutes', CHMP plenary meeting 23-26 June 2008, London 22nd July 2008, EMEA/112634/2009 Rev. 1

³⁶¹ *Ibidem*

³⁶² *Ibidem*

³⁶³ European Medicines Agency – 'Committee for Medicinal Products for Human Use: Final Minutes', CHMP plenary meeting 20-23 October 2008, London 28th 2008, EMEA/112633/2009 Rev.1

³⁶⁴ *Ibidem*

The sequence of events just described shows how under conditions of 'crisis' the relationship between the Rapporteur and the CHMP can be affected. As concerns over Acomplia increased, the Committee decided to consult external scientific experts (SAG), the assessment of which signalled a new, more complicated future for this drug. One of the important aspects about the SAG meeting is that it weakened the position of the Rapporteur. From that moment on, what mattered was what the experts concluded. The Rapporteur became a 'normal' member of the Committee and the SAG effectively played the role of the CHMP. The Committee's demand for additional expertise under conditions of crisis can be understood as translating a certain lack of faith in the traditional, Rapporteur-based evaluation process. Finally, the passive role of the Commission in this process deserves to be noted. While the decision to suspend the marketing authorisation of Acomplia had to be taken by the Commission, this institution's intervention was, its own officials recognise it, not more than a formalistic one.³⁶⁵ The request to reconsider the risk benefit balance of Acomplia under Article 20 of the Regulation came not from the Commission's reassessment of the product's risks; it originated from the will of the CHMP to open a new page in the Acomplia dossier. The very high risks involved in the marketing of this product did not strengthen the Commission's authority in the centralised procedure, but actually weakened it further. The next section explores why this happens, and reflects on the difficult relationship between complex products and structures of political accountability.

7- The EMA and the role of the Commission in the centralised procedure

The EMA, it should be repeated, has no legal authority to grant marketing authorisations to medicinal products. That responsibility falls on the Commission, in cooperation with the Standing Committee on Medicines Products for Human Use. The fact, however, is also that since this (centralised) procedure was introduced (15 years ago) the Commission has never rejected an EMA recommendation for a centralised authorisation of a medicinal product.³⁶⁶ In practice what happens is that the Commission adopts a draft marketing authorisation decision on the basis of a CHMP opinion, and the Standing Committee approves these measures without contestation. During the 15 days which the Commission has to turn the EMA's recommendation into a draft decision, its role has been confined to administrative details, such as the assignment of a Community registration number to the medicinal product waiting to be granted a marketing authorisation.³⁶⁷ The EMA and the Commission accept that this is how the system works.³⁶⁸ In the words of a Commission official, this institution's job "is not to re-do the scientific assessments which the EMA was created to perform".³⁶⁹

³⁶⁵ [Interview]: Respondent 1b (Commission)

³⁶⁶ *Ibidem*

³⁶⁷ See EU Commission website for more details on this:

http://ec.europa.eu/enterprise/pharmaceuticals/procedure/cproc_en.htm

³⁶⁸ [Interview]: Respondents 1b (Commission) and 3b (EMA)

³⁶⁹ [Interview]: Respondent 1b (Commission)

There is also an issue about the role of the Commission in the centralised procedure *before* the CHMP opinions are provided. The Commission has a number of powers which enable it to play a role in the management structures of this agency, which may raise a fear that this institution might use that leverage to interfere with technical aspects of EMA's own work.³⁷⁰ According to senior EMA officials, however, this concern has not materialised.³⁷¹ The Commission accepts that its role in the centralised procedure authorisations has essentially been a "legal and procedural one".³⁷² The 'worries' of the Commission in what the centralised procedure is concerned are therefore formal in nature; they do not touch on the substantive assessment of the products. There may be good reasons for the Commission to show this type of institutional restraint (as we shall see below). Still, the automatic acceptance of EMA expert opinions on marketing authorisations by the Commission emphasises the importance of the 'technological' interactions within the Agency (and its problems). It underlines that the institutional system lacks dynamic controls on the power of the Rapporteur. Those (deliberative) dysfunctions are not exposed to any clear institutional challenge.

While this is recognised to be an "exceptional" case, there has been at least one case (however) where the Commission in fact discussed the approval of a product with the EMA before the opinion of the CHMP had been issued.³⁷³ This happened with Yondelis, a medicine "used to treat patients with advanced soft tissue sarcoma, a type of cancer that develops from the soft, supporting tissues of the body."³⁷⁴ While the CHMP considered the approval of Yondelis in 2003 - a product which had been designated an "orphan medicine" (used for rare diseases) - the Commission was being asked by some patient groups to authorise this medicine because it would respond to an unmet medical need.³⁷⁵ Under these circumstances, the Commission had conversations with the EMA to consider whether the product could be approved. In July of 2003, however, the CHMP (at that time it was called CPMP) gave a negative opinion on the granting of a marketing authorisation to Yondelis, arguing that there existed "critical concerns on the methodology used" and that the efficacy of its

³⁷⁰ To begin with, the Commission has two representatives on the Management Board of the EMA. The Management Board (the mission of which is to supervise the activities of the Agency, deal with budgetary and planning matters and appoint of the Director of the Agency and monitor its performance) also integrates one representative per Member State (27), two members from the European Parliament, two representatives from patient's organisations, one representative from doctors' and another one from veterinary organisations. Secondly, the appointment of the Executive Director of the EMA by the Management Board is constrained by the fact that the Commission proposes the name of the person and writes the list of candidates for the job, proposed following a call for expressions of interest. Another significant instrument in the interaction between the Commission and the EMA is the possibility of the former to attend all meetings of the committees, working parties and scientific advisory groups. See: Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, *OJ L 136*, 30.4.2004, p. 1–33

³⁷¹ [Interview]: Respondent 3b (EMA)

³⁷² [Interview]: Respondent 1b (Commission)

³⁷³ *Ibidem*

³⁷⁴ *Ibidem*. See: European Medicines Agency – 'European Public Assessment Report for Yondelis – Summary for the Public', EMEA/H/C/773

³⁷⁵ [Interview]: Respondent 1b (Commission)

active substance (trabectedin) in the proposed indication “could not be established”.³⁷⁶ A few years later, the company which developed this medicine re-applied for a centralised marketing authorisation and this time it was more successful. In a July 2007 meeting, the CHMP issued a positive opinion to Yondelis under “exceptional circumstances”.³⁷⁷ ‘Yondelis’ suggests that the dialogue with the Commission does not really change much in what the regulatory approach of the EMA with respect to particular dossiers turns out to be. Despite the Commission “pressures” in this case, the CHMP still rejected the granting of a marketing authorisation to the product and only a few years later (once these CHMP worries had been addressed) did the Committee change its opinion. Moreover, the Commission’s intervention in Yondelis seems arbitrary and rather odd. It raises questions about this institution’s interest in this particular dossier. It is also problematic in that appears to reflect sensitivity towards particular interest groups.

Conclusion

The institutional structures of the centralised procedure and of the European Medicines Agency draw attention to an EU ‘problem’ of (regulatory) capacity in this system. The EMA lacks the resources to perform the scientific evaluation of the medicines itself and therefore has to outsource this work to the national authorities, via the Rapporteurs. Meanwhile, the organisation of those processes also seeks to ensure the involvement of a wider range of actors (i.e. national competent authorities) in the deliberative process and sustain controls on the scientific work that is ‘shipped out’ to the national authorities. We have seen, however, that the dynamic and fluid nature of these activities have generated a more imbalanced and asymmetric model. The power of the Rapporteur is very difficult to control and ‘checks and balances’ within the process are in fact very weak. One of the difficulties with the way in which the institutional arrangement has been readjusted is that this ‘move’ was (to a certain extent at least) unexpected. As such, the formal checks on the EMA do not account for this new type of institutional concern. The Commission’s ‘legalistic’ and external role in the EMA (centralised procedure) system does not respond to this difficulty, it crystallises it.

The reflection on what type of checks and balances would help in this context is therefore important. One way to start thinking about the ‘solution’ to these problems could be through the lens of the European Ombudsman. If the Ombudsman receives a complaint regarding the EMA’s handling of a certain dossier, his ‘office’ should investigate the matter and ask appropriate questions to the Agency. That may induce the Agency to go back and reflect on how the relevant issues were considered internally and what sort of problems might have existed. One effect which that may have is a certain recalibration in the deliberative process. The action of the Ombudsman might allow the CHMP to

³⁷⁶ European Medicines Agency – ‘Committee for Proprietary Medicinal Products: Summary of opinion for Yondelis’, London, 20th November 2003, CPMP/5706/03

³⁷⁷ Approval under “exceptional circumstances” means that because the disease is rare, it was not possible for the Committee to obtain complete information the product under consideration. In such cases, the EMA will review, every year, new information that becomes available so as to consider whether the “approval can be converted into a normal one”. See: <http://www.emea.europa.eu/Patients/authorised.htm>

acquire a stronger hold of the decision-making process; it may allow for internal institutional reflection and would (potentially) reduce the constraints on the scientific committee's dialogues with the Rapporteur. The Ombudsman would therefore work as an outside institutional pressure which could hopefully give added energy to the internal (EMA) procedures that have become destabilised. If the Ombudsman is to be considered as a form of dealing with the dynamic challenges (of the EMA and of the centralised procedure) that would also recognise that 'more' controls within the EMA would not necessarily be a good idea. The fact that the centralised procedure already includes a Co-Rapporteur (the 'real' control in this system) is important in this respect. Instead of increasing the layers of internal checks (which in this case, run a serious risk of being neglected) it may consequently be preferable to consider (namely via the Ombudsman) other dynamic ways of injecting vitality to the (deliberative) procedures which already exist.

Chapter III

Data gaps and EU capacity constraints: the ECHA and the expansion of the authorisation procedure

Introduction

The European approach to the regulation of the chemicals sector has undergone major changes since 2006, when the REACH program (Registration, Evaluation and Authorisation of Chemicals) was introduced.³⁷⁸ REACH is a regulatory initiative that requires the 'registration' of all the substances on the market, subjects some of them to 'evaluation', and imposes the 'authorisation' of the most dangerous substances. The REACH Regulation has also created the European Chemicals Agency (ECHA) to administer the new regime and provide technical advice to the Commission.³⁷⁹ The role of ECHA is to receive and accept the registrations submitted by the industry, to check the quality of the registration dossiers and to submit technical opinions to the Commission on applications for EU authorisation. Moreover, ECHA has to manage the authorisation procedure, a complex and staged process that requires the 'identification' of the dangerous substances and their subsequent 'prioritisation' for authorisation. Importantly, the EU authorisation procedure is formally independent from the registration and evaluation of the substances. Authorisation may be initiated even before the registration of a substance (where enough information is available). At the same time, the previous registration of the substances and their subsequent evaluation through the ECHA system is meant to ensure that the required data is received and analysed, and that authorisation may then really target the most problematic and riskier chemicals on the market.

We shall see below that the ECHA procedures are not working as expected. The problem starts with the industry registrations, which are often of poor quality and companies are failing to provide all the important substance data. What is usually missing in the registration dossiers (we shall see) are descriptions of how exactly the substances are being used on the market, across Europe. The ECHA was meant to control these dynamics (through the evaluation procedures) but it has limited resources to do so and the dimension and complexity of the EU registration process (and problems) is something that can overwhelm an agency. The chapter shows that due to fundamental problems in the way access to chemical data works, the stability of the ECHA internal procedures (and in particular the role of the EU authorisation procedure) has been deeply affected. Based on a study of ECHA's handling of 'Diarsenic Trioxide' (a substance which has been targeted for EU authorisation) it will be noted that 'authorisation' can be used primarily as a way to acquire more data on the substances, as a form of dealing with doubts about what the risks of certain substances 'really are'. To be sure, the use of the EU authorisation procedure for fact finding purposes is not without

³⁷⁸ Regulation (EC) No 1907/2006 of the European Parliament and of the Council, *OJ L 396*, 30.12.2006, p. 1–849

³⁷⁹ *Ibidem*, Article 75

problems. Authorisation was created to consider and structure bans on the most dangerous substances, not to offer a standard way to learn about a wide-range of chemicals and their risks. Moreover, the dependence of ECHA on the 'authorisation system' presents two sets of issues. First, this move does not sustain a credible strategy for the effectiveness of the (regulatory) policy. It is hardly conceivable that the authorisation procedure can grow enough to actually deal with all the data gaps. Secondly, the sort of legal and policy entrepreneurship that the Agency is engaging in creates a 'checks and balances' difficulty. The use of the authorisation procedure for data collection purposes imposes tough regulatory requirements on the industry (small and medium companies, in particular, may suffer) and there are no real controls on this 'readjustment' of the system.

There is, as a consequence, a strong case to be made in favour of the reform of these procedures. The changes should be focused on two main pillars, or problems: the analysis of the chemical data (i.e. the identification of data gaps in the industry registrations) and a new enforcement strategy to deal with serious cases of non-compliance. With regard to the first point, the chapter suggests that the ECHA integrates environmental NGOs in the system as patrols, so that they may contribute to the review of the dossiers submitted by industry. The inclusion of environmental groups in the regulatory process is highly advantageous in that it provides the system with much needed (external) regulatory capacities, giving new energy to the data reviews and controls on industry. Secondly, the reform of the ECHA procedures needs to tackle an enforcement issue. Currently, chemical companies have weak incentives to comply with the EU registrations fully and to provide the Agency with all the hazard information. That creates a major challenge for this regulatory system for even if the industry faces own challenges in complying with the new registration requirements, the success of the policy depends to a large extent on the ability to make registration work and lead companies towards an ever more collaborative attitude. It is consequently recommended that a reformed system includes a system of fines to address serious cases of (registration) non-compliance. The responsibility to impose fines would fall on the Commission (and ECHA could make recommendations on this, including the opinions of the environmental groups involved in the relevant dossier reviews). Such a move would put significant pressure on the industry to provide the data, and would then (hopefully) also reduce the current dependence on the authorisation procedure for purposes which are outside its intended remit. This 'solution' therefore addresses questions on the overall effectiveness of the policy as well as risks to the stability and predictability of the internal processes of the Agency.

The chapter is structured as follows: it begins by considering the pre-REACH European approach to the regulation of chemicals and its problems. Secondly, the registration process and the ECHA's administrative management of that system will be considered. Thirdly, the quality of the registration dossiers and the constraints on the EU public 'evaluation' structures shall be explored. Fourthly, the role of the EU authorisation procedure is considered (and the case-study is also developed). The final section explains why the reform of the current regulatory procedures would be important.

1- REACH and the 'burden of the past'

Chemicals are an important part of our daily lives. In addition to their intended purposes, a great number of these substances also generate serious risks to public health and the environment.³⁸⁰ The contribution of this sector to the European economy is also significant.³⁸¹ Some of the world's leading multinational chemical firms are based in the EU and more than 36,000 SMEs are active in this territory.³⁸²

The development of a common regulatory regime for chemicals in the EU has been a concern at least since the 1980s. Before the entry into force of REACH (2007) the EU regulatory regime relied on a series of Directives and Regulations.³⁸³ That model was essentially shaped by a distinction between 'existing' and 'new' substances.³⁸⁴ The 'new' substances were those entering the EU market after September 1981, while the 'existing' ones were chemicals which had been reported as being on the EU market between January 1971 and September 1981.³⁸⁵ New substances (i.e. those introduced on the EU market after 1981) had to undergo a notification requirement. This was designed to help EU authorities acquire more information on chemicals and prepare some sort of common risk management model.³⁸⁶ Market access therefore became dependent on the notification of a dossier to the competent authority of the Member State where the manufacturer (or importer) wished to initiate the marketing of the substance. This 'national notification' then generated one-stop shop rights as it was valid in the whole EU territory. The notification duties for new chemicals were tough (for the industry) as they started from a very low threshold (production or import in quantities exceeding 10kg per year). National authorities were also asked to perform risk assessments (since the early 1990s) based on the dossiers submitted by the industry, according to new EU risk standards approved during that period.³⁸⁷ In case EU level risk management measures were required this would be done through (legislative) restrictions on marketing and use.

However, for chemicals that were in circulation on the EU market prior to 1981, this notification system did not apply. It was considered that a general requirement to supply data and to carry out

³⁸⁰ European Commission, 'White Paper: Strategy for a future Chemicals Policy', Brussels, 27.2.2001, COM (2001) 88 final, p. 4

³⁸¹ *Ibidem*

³⁸² *Ibidem*

³⁸³ See: V. Heyvaert, *Coping With Uncertainty: The Regulation of Chemicals in the European Union* (PhD Dissertation, European University Institute, Florence, Italy, 1999)

³⁸⁴ In this context, a substance "means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition." See: Article 3 (1) REACH Regulation (cited above)

³⁸⁵ See: V. Heyvaert, *The EU chemicals policy: towards inclusive governance?*, LSE Law, Society and Economy Working Papers 07/2008. Department of Law, London School of Economics and Political Science, London, UK, p. 2 – 3

³⁸⁶ *Ibidem*, p. 3

³⁸⁷ *Ibidem*

tests (for those substances) was “too onerous and potentially disruptive to the economy.”³⁸⁸ The consequence was that the regulatory regime was split, favoring old over new substances.³⁸⁹ According to Heyvaert, this did not favor innovation and meanwhile failed to ensure a strong grip on old chemicals, which “tend to pose greater risks” than newer ones.³⁹⁰ Moreover, while there were 3.800 ‘new’ chemicals when REACH was introduced, the number of existing substances was much higher (about 100.000 chemicals).³⁹¹ In the 1990s ‘data gathering’ system established to deal with ‘existing’ substances (through Regulation EEC 793/93), manufacturers and importers had to report available data on their chemicals to the Commission (and then these submissions were gathered by the European Chemicals Bureau).³⁹² It was based on this information that the prioritizing of the dangerous chemicals began: the Commission prepared priority lists for the higher risk chemicals and these substances were subsequently assigned to the Member States for (risk) assessment.³⁹³ National authorities (acting as ‘Rapporteurs’) carried out risk evaluations and reported the results back to the Commission. Where risk management measures were required, this had to be done legislatively (namely, under the under the marketing and use restrictions Directive).³⁹⁴ Until 2006, the Commission developed four priority lists (including 141 ‘existing’ high-volume substances).³⁹⁵ Only 70 risk assessment reports had been concluded by that time (and the latter usually ended with a note saying that more information was needed for risk control measures to be put in place).³⁹⁶ Moreover, the ‘data-bank’ European Chemicals Bureau observed, in 1999, that basic data on ‘high production volume’ chemicals was only available for 14% of the substances (while for 21% there was no data whatsoever).³⁹⁷ All in all, while the notification procedure for new substances had positive results,³⁹⁸ the regulation of existing substances failed to work. The industry had no real incentive to comply with the data submission regime and the decentralized risks assessment process was too slow and ineffective.³⁹⁹

³⁸⁸ *Ibidem*

³⁸⁹ *Ibidem*

³⁹⁰ *Ibidem*

³⁹¹ European Commission – Environment Directorate General, ‘REACH in brief’, October 2007, p. 3

³⁹² Council Regulation (EEC) No 793/93 of 23 March 1993, *OJ L 84*, 5.4.1993, p. 1–75

³⁹³ *Supra* 385, [Heyvaert, LSE 2008], p. 4

³⁹⁴ *Ibidem*, p. 3-4. Regarding the concerned legislation, see: Council Directive 76/769/EEC, *OJ L 262*, 27.9.1976, p. 201–203

³⁹⁵ L. Koch and N. A. Ashford, *Rethinking the role of information in chemicals policy: implications for TSCA and REACH*, *Journal of Cleaner Production*, Vol. 14, No. 1, 2006, p. 39

³⁹⁶ *Ibidem*

³⁹⁷ *Ibidem*

³⁹⁸ *Supra* 385, [Heyvaert, LSE 2008], p. 4

³⁹⁹ *Ibidem*

The formal structures of REACH

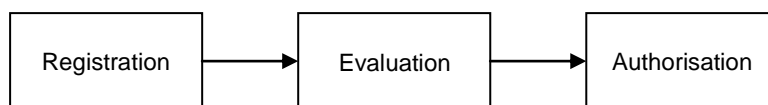


Figure 1: the tripartite and sequential structure of REACH

In June 1999, the Council adopted a series of conclusions on a new European chemicals strategy, which then informed the Commission White Paper (2001) outlining a 'Strategy for a future Chemicals Policy'.⁴⁰⁰ Here, the Commission proposes to establish 'REACH' (for the Registration, Evaluation and Authorisation of Chemicals). Following years of negotiations, REACH entered into force in 1 June 2007.⁴⁰¹

REACH replaced a series of legislative acts by one Regulation.⁴⁰² It puts an end to the distinction between 'new' and 'existing' substances that characterised the previous regulatory regime, establishing instead a single system for all chemicals.⁴⁰³ It seeks to have them all registered, evaluated and to subject the most dangerous ones to a new authorisation requirement.⁴⁰⁴ Only chemical substances produced or imported in quantities equal or above 1 tonne per year fall under REACH.⁴⁰⁵ This threshold is actually higher than the previous notification requirement for 'new' substances (which started at 10kg per year) and in practice it means that it requires the registration of about 30.000 chemicals (most of which are 'old' ones).⁴⁰⁶ Substances are now described as non-phase-in (i.e. those not produced or marketed prior to the entry into force of REACH) and phase-in (which are effectively the older ones).⁴⁰⁷ The previous category of 'new substances' (post-1981), which had undergone notification duties, are immediately considered to be part of REACH and their former registration number (in the EILINCS list) is converted into a new identification reference.⁴⁰⁸ Whereas REACH targets all chemicals (old and new), the big challenge (as explained above) is to overcome the data gaps on the former "existing substances".⁴⁰⁹

⁴⁰⁰ Supra 380, [EU Commission: Chemicals' White Paper], p. 6

⁴⁰¹ Supra 378, [REACH Regulation 2006]

⁴⁰² *Ibidem*

⁴⁰³ *Ibidem*, Article 5

⁴⁰⁴ *Ibidem*, Articles 5, 40 and 55

⁴⁰⁵ *Ibidem*, Article 6 (1)

⁴⁰⁶ Supra 380, [EU Commission: Chemicals' White Paper], p. 6

⁴⁰⁷ Supra 378, [REACH Regulation 2006], Article 12 (1) - (a). More rigorously, 'phase-in' substances are those listed in the EINECS (i.e. chemicals reported as being on the EU market between January 1971 and September 1981), those that have been manufactured in the EU but not placed on the market in the previous 15 years as well as chemicals known as 'no longer polymers' (Directive 67/548)

⁴⁰⁸ *Ibidem*, Annex II (3.5)

⁴⁰⁹ See: J. Scott, *From Brussels with Love: The transatlantic Travels of European Law and the Chemistry of Regulatory Attraction*, American Journal of Comparative Law, Vol. 57, No. 4, 2009, p. 898

The starting point of REACH is therefore the registration of all substances above the 1 tonne threshold (see details below).⁴¹⁰ While registration duties vary according to the properties of the chemicals and their level of production or import (see below), these provisions generally “require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures.”⁴¹¹ It is therefore not just about compiling data; it also involves an assessment (by the industry) of the risks presented by “their” substances and how these can be tackled. Registration is also a very demanding process for the industry: it involves thousands of companies and it establishes new and tough regulatory requirements which can be difficult to cope with.⁴¹²

Secondly, the ‘evaluation’ procedures may be activated as soon as a substance has been registered. Evaluation exists to check the quality of the registration dossiers, to ask the industry to correct and improve the data which they have submitted and to develop a better understanding on the substances’ risks.⁴¹³ There are two types of evaluations: dossier evaluations and substance evaluations.⁴¹⁴ The investigation of the *dossiers* can involve compliance checks (i.e. assessing whether the registrations comply with the REACH legal requirements) and examinations of the industry’s testing proposals by the ECHA secretariat.⁴¹⁵ The REACH Regulation only demands that the ECHA performs compliance checks on at least 5% of the total number of registration dossiers received.⁴¹⁶ The substance evaluations, on the other hand, focus on substances that raise an initial concern, and which therefore require “further evaluation”.⁴¹⁷ This responsibility falls on the national authorities, which are assigned specific substances for the purpose of that examination.⁴¹⁸ The substance evaluation process has not yet started, but will begin soon (January 2012).⁴¹⁹

Thirdly, REACH introduces an authorisation procedure targeting the most dangerous substances on the EU market.⁴²⁰ The institutional selection of substances for authorisation is formally independent from the registration and the evaluation processes; it is carried out through “identification” of substances of very high concern (which are included in a candidate list) and their subsequent

⁴¹⁰ Supra 378, [REACH Regulation 2006], Articles 5 and 6

⁴¹¹ *Ibidem*, Recital (19)

⁴¹² The burden of REACH for the industry can be significant. The estimated direct costs to the chemicals industry of REACH are € 2.3 billion over the first 11 years. For downstream users of chemicals (whose responsibilities are also strengthened by REACH, as we shall see below), the estimated costs can go up to € 2.9 billion. Counting direct and indirect costs to the industry, the estimated overall costs of this program may reach € 5.2 billion (over a period of 11 to 15 years). On these figures, see: European Commission – Environment Directorate General, ‘REACH in brief’, October 2007

⁴¹³ Supra 378, [REACH Regulation 2006], Articles 40, 41 and 44

⁴¹⁴ *Ibidem*, Articles 51 and 52

⁴¹⁵ *Ibidem*, Article 40 and 41

⁴¹⁶ *Ibidem*

⁴¹⁷ *Ibidem*, Article 44

⁴¹⁸ *Ibidem*, Article 45

⁴¹⁹ *Ibidem*, Article 44 (2)

⁴²⁰ *Ibidem*, Article 60

“prioritisation” for authorisation.⁴²¹ These SVHC substances are eventually included in the Annex XIV of the Regulation and can only be approved if their risks are considered to be “adequately controlled” or if the socio-economic benefits associated with them outweigh the risks and no safer substitutes are available.⁴²² The expert opinions of the ECHA on applications for authorisation are prepared by two technical bodies: the Risk Assessment Committee (RAC) and the Socio-Economic Committee (SEAC).⁴²³ The importance of the socio-economic assessments and of the substitution investigations suggests that authorisation is not just about banning or approving substances in the EU market. It constitutes a series of administrative processes designed to generate more data on the substances’ risks and about the overall technical and social context in which they are used.

2- The complexities of registration and the constraints on the ECHA

Registration fundamentally changes the relationship between private and public actors in EU regulation of chemicals. The initial reliance on the industry for the provision of data on the substances via the registration system may have important advantages, but it is not without problems. The big challenge has been (as we shall see below when looking at the evaluation of the dossiers) the quality of the data provided by industry during registration. Moreover, the registration process requires much collaboration within the industry, particularly for data sharing and joint submission of dossiers, and that has not always gone down well. The level of administrative support which is needed at this stage largely exceeds what had been expected and creates difficulties. We shall see that conflicts within the industry during registration may affect the quality of the dossiers, consume ECHA technical resources and attract disputes to the Agency itself.

Chemicals produced or imported into the EU in quantities exceeding 1 tonne per year have to be registered with the ECHA.⁴²⁴ This system operates on the basis of a series of deadlines, prioritising substances produced or imported in higher quantities as well as those with dangerous intrinsic properties (see figure 1, below).⁴²⁵ After the lapse of the applicable (final) registration date, substances cannot be marketed unless they have been registered in the ECHA system (‘no data, no market’).⁴²⁶ For the companies, registration can involve either the preparation of a technical dossier or a (more demanding) chemical safety report.⁴²⁷ These are distinguished by a tonnage trigger. The technical dossier (which applies for substances produced or imported in quantities between 1 and 10 tonnes) essentially involves the communication of adequate information on the substances.⁴²⁸ In that dossier, data on the properties, uses and classification of the substance (as well as guidance on safe

⁴²¹ *Ibidem*, Article 58 and 59

⁴²² *Ibidem*, Article 60 (2) and (4)

⁴²³ *Ibidem*, Article 76 (1) c, d

⁴²⁴ *Ibidem*, Article 6 (1)

⁴²⁵ *Ibidem*, Article 23. See also the Recital of the Regulation (paragraph 42)

⁴²⁶ *Ibidem*, Article 5

⁴²⁷ *Ibidem*, Article 10

⁴²⁸ *Ibidem*, Article 10 (a)

use) should be found. On the other hand, a chemical safety report (which applies to substances manufactured or imported in quantities exceeding 10 tonnes per year) includes not just data about the properties of the substance and the exposure profiles, but also the set of risk reduction measures that need to be put in place to ensure safe production and use.⁴²⁹ In practice, however, the majority of the substances do not require the stricter chemical safety report registration duties as most of them are produced or imported into Europe below the 10 tonnes per year level (1 - 10 t/y = 17,500 substances; 10-100 t/y = 4977 substances; 100-1000 t/y = 2641 substances; and > 1000 t/y = 7204 substances).⁴³⁰

The very large dimension of the registration process suggests that the challenges for the ECHA, in terms of organizing the system and then checking the quality of the dossiers, are significant. Overall, about 30.000 chemicals will be registered over a period of 11 years (until 2018).⁴³¹ Until 2010 (the first registration deadline was on November of that year) ECHA had received 25.000 registration dossiers for 4.300 chemical substances (there can be several registrants of the same chemical substance, as we shall see below).⁴³² Out of these almost 4.300 chemicals, 3.400 were phase-in (i.e. older) substances.⁴³³ Regarding this latter (phase-in) category, the first registration deadline targeted: a) substances produced or imported in quantities of 1000 tonnes or more per year; b) 'low production or import' CMR chemicals reaching the 1 tonne threshold (i.e. carcinogenic, mutagenic or toxic for reproduction, category 1 or 2); and c) substances above the 100 tonne threshold classified as 'very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment'.⁴³⁴ The first (November 2010) registration deadline therefore mostly affected substances produced or imported above 1000 tonnes per year (very high production) in addition to the lower production CMRs ("very high concern" chemicals). In 2010 there were 17.459 registrations for the >1000 t/yr (phase-in) group and 765 for the 1-10 t/yr category.⁴³⁵ As a consequence, the great majority of the dossiers were submitted by "large industry" (about 87%).⁴³⁶ More registrations from SMEs are expected starting from the May 2013 registration deadline.

Initially, it was hoped that after the submission of the registration dossiers, the setting up of automated IT systems by the ECHA would ensure that the need for ECHA human intervention at this level would be kept to a minimum.⁴³⁷ Registrations only had to undergo a simple electronic check to verify completeness.⁴³⁸ But the dynamics of registration soon showed that the process would be much more

⁴²⁹ *Ibidem*, Article 10 (b)

⁴³⁰ *Supra* 395, [Koch and Ashford], p. 38

⁴³¹ *Supra* 378, [REACH Regulation 2006], Article 23

⁴³² European Chemicals Agency – 2010 General Report: The Year of Registration, ECHA-11-A-01-EN - MB/03/2011, 24 March 2011, p. 3

⁴³³ *Ibidem*, p. 7

⁴³⁴ European Chemicals Agency – 'Guidance on Registration', January 2011, Version 1.6, ECHA-11-G-03-EN, p. 49

⁴³⁵ European Chemicals Agency – 'Evaluation Progress Report 2010', ECHA-11-R-001-EN, 28/02/2011, p. 10

⁴³⁶ *Supra* 432, [Annual Report 2010], p. 10

⁴³⁷ European Chemicals Agency – Multiannual Staff Policy Plan 2010-2012, Doc: MB/03/2009 final, Helsinki, 26.02.2009, p. 11

⁴³⁸ *Supra* 378, [REACH Regulation 2006], Recital (44)

complex and demanding for the Agency. This is mainly because during registration companies have obligations to share data and this often results in disputes between them.⁴³⁹ Data sharing is organised in the so called “Substance Information Exchange Forums” (SIEF).⁴⁴⁰ For every substance there should be one SIEF. Members of the SIEFs include “all relevant actors submitting information to the Agency on the same phase-in substance” (i.e. mainly potential registrants but also downstream users and third parties).⁴⁴¹

The idea behind these platforms is that potential registrants can see what studies are available and request access to them where needed (for registration).⁴⁴² The owners of the studies have to react to requests for data sharing and seek financial compensation in a fair, transparent and non-discriminatory way.⁴⁴³ The organisation of companies in the SIEFs also facilitates the joint submission of the registration dossier.⁴⁴⁴ Within each SIEF, a ‘lead registrant’ is selected to submit the parts of the data that have to be sent jointly, and then each registrant will be responsible for sending the remaining information to the ECHA.⁴⁴⁵ By July 2011, there were 3280 SIEFs in operation.⁴⁴⁶ One of the difficulties associated with the SIEFs is that leading these platforms has costs for their ‘leaders’ and can be difficult. ECHA has noted that “[f]eedback from industry associations indicated that some registrants were reluctant to take over the lead registrant responsibilities due to the amount of resources needed for administering the SIEF and preparing the joint submission as well as the lack of understanding of the legal obligations.”⁴⁴⁷

Moreover, the occurrence of many data sharing disputes has forced the ECHA to intervene strongly in this area. ECHA notes that “severe problems among the registrants” relate to “data-sharing in general and cost-sharing in particular”.⁴⁴⁸ In order to avoid the duplication of tests with vertebrate animals, ECHA tries to force agreement between those who have already made those tests and others who wish to get access to them. But if the concerned parties fail to agree on the terms of the data sharing, two things may happen. First, if the owner of a study (with vertebrate animals) “refuses to provide either proof of the cost of that study or the study itself” to another SIEF participant, he will not be able to register the substance (unless the ECHA allows him to).⁴⁴⁹ In cases where the study that is being requested by a potential registrant is included in a dossier that has already been registered (and,

⁴³⁹ *Ibidem*, Article 25

⁴⁴⁰ *Ibidem*, Article 29

⁴⁴¹ *Ibidem*, Recital (54)

⁴⁴² *Ibidem*, Article 29 (2)

⁴⁴³ *Ibidem*, Article 27 (3)

⁴⁴⁴ *Ibidem*, Article 11

⁴⁴⁵ *Ibidem*

⁴⁴⁶ Substance Information Exchange Forum (SIEF), weekly update of Active Lead Registrants, available online: http://echa.europa.eu/sief_en.asp

⁴⁴⁷ European Chemicals Agency – ‘The Operation of REACH and CLP’, 2011, ECHA-11-R-003-EN, p. 12

⁴⁴⁸ European Chemicals Agency – ‘General Report 2010: the year of Registration’, ECHA-11-A-01-EN, MB/03/2011, 2011, p. 8

⁴⁴⁹ *Supra* 378, [REACH Regulation 2006], Article 30 (3). See also: European Chemicals Agency, ‘Questions and Answers on data sharing and related disputes’, 30/07/2010, ECHA-10-QA-04-EN, p. 1

again, the parties cannot agree on the sharing of the data or on the level of compensation), the Agency has to “perform an assessment” on whether one of the parties has failed “to make every effort” to find a solution to the dispute at hand.⁴⁵⁰ ECHA may then decide to grant the potential registrant permission to refer to the information that was requested (subject to financial compensation to the party that performed the study).⁴⁵¹ In this context, ECHA is expecting that as we approach the subsequent registration deadlines, its decisions on data sharing will often be followed by appeals (through the internal Board of Appeal)⁴⁵² and that this will then imply a “substantial amount of work” for its legal defence.⁴⁵³

As a consequence of these problems, the Agency says that while it still hopes to achieve “fully automated registrations and workflows”, the pre-registration experience has shown that “failure or insufficient functioning of IT systems can have a dramatic impact on the need for human intervention, specifically for support at technical-administrative level.”⁴⁵⁴ It also observes that while “initially it was assumed that technical compliance checks and invoicing would be almost entirely automated procedures”, in fact “only a partial automation was possible” and “many technical and administrative verification steps of dossiers are required, especially for the dossiers submitted by the lead registrants of each SIEF.”⁴⁵⁵

3 - The quality of the registrations and the public controls in ‘evaluation’

While the official discourse at the ECHA is that the industry is ‘living up’ to its challenges, the fact is also that many mistakes and shortcomings have been identified in the registrations. One of the central concerns is the quality of the dossiers, which is often poor.⁴⁵⁶ According to an ECHA official, what is missing is often the description of “what exactly is being done with the substances.”⁴⁵⁷ While compliance checks “confirm whether registrants have fulfilled their obligations with regard to REACH information requirements in many aspects of hazard and exposure information”, ECHA notes that until this moment “these initial checks have indicated that a significant proportion of dossiers have shortcomings and still need to be improved with further information”.⁴⁵⁸ More specifically: while “many endpoint records and exposure scenarios are filled with valid information”, the registrants “often did not provide dossiers in compliance with all the information requirements.”⁴⁵⁹ According to the ECHA,

⁴⁵⁰ European Chemicals Agency, ‘Questions and Answers on data sharing and related disputes’, 30/07/2010, ECHA-10-QA-04-EN, p. 9

⁴⁵¹ Supra 378, [REACH Regulation 2006], Article 30 (3)

⁴⁵² *Ibidem*, Article 89

⁴⁵³ European Chemicals Agency, Work Programme for 2011, Helsinki, 30 September 2010, Doc: MB/48/2010 final, p. 10-11

⁴⁵⁴ Supra 437, [Multiannual Staff Policy Plan 2010-2012], p.11-12

⁴⁵⁵ *Ibidem*

⁴⁵⁶ [Interview]: Respondent 1a (ECHA). See also: European Chemicals Agency – ‘The Operation of REACH and CLP’, 2011, ECHA-11-R-003-EN, p. 26

⁴⁵⁷ [Interview]: Respondent 1a (ECHA)

⁴⁵⁸ Supra 447, [‘The Operation of REACH and CLP’, 2011], p. 26

⁴⁵⁹ *Ibidem*

the industry is generally unable to justify why new studies are *not* necessary as a way to assess the proprieties of the substances and their effects on humans and on the environment.⁴⁶⁰

The ECHA is meant to conduct compliance checks on 5% of the registration dossiers (for each tonnage band). The Agency performs random and non-random checks.⁴⁶¹ While ECHA has defined “prioritisation criteria” to select the dossiers subject to compliance checks;⁴⁶² it is also considered “highly recommended” that this is complemented by a system where dossiers are selected “mainly at random in the first years after entering into force of REACH in order to be able to identify the main reasons for non-compliance.”⁴⁶³ This (5%) minimum target means that few dossiers are actually checked. There is also an issue about the intensity of the ECHA’s scrutiny of those dossiers targeted for compliance review. According to an agency official, while “any registrant who has submitted an incompliant dossier is in breach of the law and may face regulatory action, it has to be acknowledged that it was and remains challenging for companies to comply with the new requirements, both in terms of workload and understanding and complying with the novel regulatory approach imposed by REACH.”⁴⁶⁴ The ECHA seems to prefer “active feedback and stressing the fact that industry remains responsible for the content of their dossiers, also after the registration deadline” instead of a bolder strategy targeted at problematic dossiers.⁴⁶⁵

When ECHA performs dossier compliance checks, it can choose to do three things: 1) no further action (when the information is considered sufficient); 2) submission of a ‘quality observation letter’ to the registrant (in case there are shortcomings “not necessarily related to the lack of information”); or 3) issue a ‘draft decision’ to the registrant if missing data is identified and ordering corrections to be made until a certain date.⁴⁶⁶ Data from 2010 shows that only 17 % of the evaluated dossiers were concluded with a final decision (the majority are either readily accepted or subject to a quality observation letter, which tends to focus on classification and labeling issues).⁴⁶⁷ At least until that date, the ECHA did less dossier compliance checks than required by REACH (i.e. the minimum target set by the Regulation is 5% compliance reviews for every tonnage band).⁴⁶⁸ While recent data (2011) shows that more draft decisions are being sent to the registrants when compared to previous years,⁴⁶⁹

⁴⁶⁰ *Ibidem*, p. 2

⁴⁶¹ European Chemicals Agency – ‘Guidance on Dossier and Substance Evaluation’: guidance for the implementation of REACH, June 2007, p. 42

⁴⁶² European Chemicals Agency – ‘Guidance on Priority Setting for Evaluation’: guidance for the implementation of REACH, August 2008, p. 8

⁴⁶³ *Supra* 461, [Guidance on Evaluation], p. 43

⁴⁶⁴ [Interview]: Respondent 1a (ECHA)

⁴⁶⁵ *Ibidem*

⁴⁶⁶ *Supra* 435, [Evaluation progress report 2010], p. 6

⁴⁶⁷ *Ibidem*, p. 14

⁴⁶⁸ *Supra* 378, [REACH Regulation 2006], Article 41-5

⁴⁶⁹ *Supra* 447, [The Operation of REACH and CLP], p. 26.

there are indications that the ECHA continues to do perform less compliance checks of high production substances (> 1000 tonnes per year) than it does for lower production ones.⁴⁷⁰

The ECHA dossier reviews are also very constrained processes. As the ECHA explains, the “outcome of a compliance check is a request for further information.”⁴⁷¹ The requested information “concerns specific studies on properties of the substance, or information on uses and exposure.”⁴⁷² It is noted that while “missing information elements that are used for the derivation of the risk characterisation and risk management” may to a certain extent be addressed through a draft decision, “the actual risk management measures applied or recommended by the registrants cannot be addressed or corrected by requesting further information.”⁴⁷³ The actual risk management measures will have to be adopted ‘later’ under the appropriate REACH, CLP (classification, labelling and packaging) or other legislative frameworks.⁴⁷⁴ Meanwhile, the ECHA notes that “there remain expectations that the compliance check will address such [risk management] issues.”⁴⁷⁵ This rigidity is not helpful and the ECHA now considers that the “borderlines of compliance checks versus other risk management mechanisms under REACH [...] needs further discussion with all stakeholders to be better defined.”⁴⁷⁶ This ECHA warning is important and it indicates that while the challenges involved in the assessment and management of risks in this area very fluid and dynamic, the current institutional structures are too rigid and self-contained.

‘Substance evaluations’ and the limited levels of national outsourcing

The REACH assessment processes comprise not only the review of the quality of the *dossiers*, but also a “substance evaluation” system.⁴⁷⁷ While the dossier evaluations are focused on the quality of the dossier, the substance evaluations serve to clarify an “initial concern” with the substances, to acquire more information on them and to consider whether and how that data should be used for risk management purposes.⁴⁷⁸ Unlike the evaluation of the dossiers (an ECHA responsibility), the substance evaluations will be carried out by the Member States’ competent authorities.⁴⁷⁹ The allocation of substances to particular NCAs is carried out via a Community Rolling Action Plan (CoRAP).⁴⁸⁰ This plan is currently being prepared and the substance evaluations should take-off in

⁴⁷⁰ Supra 453, [ECHA 2011 work programme], p. 14. Out of a total of 30 (phase-in) compliance checks in 2008 and 2009, only 1 compliance check was performed for a phase-in substance above the >1000t threshold. On this see: ECHA – ‘Evaluation 2009 Progress Report’, February 2010, ECHA-10-R-001-EN, p. 12-13

⁴⁷¹ Supra 447, [Operation of REACH and CLP], p. 27

⁴⁷² *Ibidem*

⁴⁷³ *Ibidem*

⁴⁷⁴ *Ibidem*

⁴⁷⁵ *Ibidem*

⁴⁷⁶ *Ibidem*

⁴⁷⁷ Supra 378, [REACH Regulation 2006], Article 44 and 45

⁴⁷⁸ Supra 461, [Guidance on Evaluation], p. 18

⁴⁷⁹ Supra 378, [REACH Regulation 2006], Article 44 and 45

⁴⁸⁰ *Ibidem*, Article 44 (2)

2012.⁴⁸¹ During the process of drafting the CoRAP, a national authority which is interested in the evaluation of a substance has to explain “the grounds for considering that the substance constitutes a risk to human health or the environment and argue why [...] the substance should be prioritised for addition to the draft Community rolling action plan [...]”.⁴⁸² While the ECHA “coordinates” the preparation of the CoRAP and the allocation of substances for different NCAs, it cannot impose particular chemicals on the national authorities.⁴⁸³

One of the most interesting aspects about the operation of this EU regulatory system is the link between internal capacity constraints and the lack of national outsourcing. During its first years of existence, the ECHA secretariat has had to manage a very demanding registration process and performed many dossier checks on those registrations. The structure of these processes and the commencement of the substance evaluations in 2012, emphasises a preference for having much of the technical work being performed ‘in-house’. Once the substance evaluations begin, however, it is likely that the regulatory burden on the national authorities will increase. The performance of a substance evaluation requires the previous assessment of the registration dossier (for quality assessment purposes) and where the ECHA secretariat has not yet done this, the national competent authority will have to do that work herself.⁴⁸⁴

The substance evaluations should suffer from many of the constraints on the ECHA *dossier* checks. When a substance evaluation is initiated, the amount of information that is available largely depends on the quality of the data that the industry has supplied when it submitted the registration dossier.⁴⁸⁵ Moreover, the substance evaluations are limited from a risk management perspective. While the substance evaluations allow national authorities to ‘prepare’ subsequent risk management strategies if that is considered necessary (see below); the actual evaluation of the substance only allows public authorities to *ask* the industry to provide more data on the substances. The national authorities are equally dependent on the industry for the provision of that information. The outcome of a substance evaluation consists of a decision on whether sufficient information is available to clarify the existing concerns and, where more information is needed, a formal decision shall be sent to the registrant.⁴⁸⁶ The enforcement of those decisions should remain difficult. We shall see below that these constraints are putting more pressure on the ECHA authorisation procedure.

⁴⁸¹ *Ibidem*

⁴⁸² Supra 461, [Guidance on Evaluation], p. 60

⁴⁸³ Supra 378, [REACH Regulation 2006], Article 44

⁴⁸⁴ Supra 461, [Guidance on Evaluation], p. 12. Considering the very demanding targets which the ECHA has set itself in terms of dossier compliance reviews (600 per year), it is likely that the national authorities responsible for substance evaluations will often have to carry out *dossier* evaluations as well

⁴⁸⁵ Supra 461, [Guidance on Evaluation], p. 18

⁴⁸⁶ *Ibidem*, p. 57

4- The expansion of the authorisation procedure and its problems

One of the new and more significant features of REACH is the introduction of an authorisation procedure targeting the most dangerous substances on the EU market.⁴⁸⁷ Once chemicals are included in the authorisation list they can only continue to be marketed if they benefit from this EU authorisation.⁴⁸⁸ But the authorisation procedure is also a complex and staged process. Its importance lies not only in the decision to keep or ban a substance on the market, but on a series of administrative steps which deal with the “identification” and “prioritisation” of substance for authorisation.⁴⁸⁹ The authorisation procedure therefore begins with the preparation of an Annex XV dossier for the identification of a substance of “very high concern” (i.e. SVHC).⁴⁹⁰ This is done either by the ECHA (on behalf of the Commission) or by an NCA (following a procedure in which other national authorities and the ECHA are given a chance to comment on the proposed Annex XV dossier).⁴⁹¹ If no comments are received or agreement is reached on a SVHC dossier, the relevant substance is included in the so-called ‘candidate list’.⁴⁹² The chemicals on the candidate list are not subject to authorisation immediately. Within this list, substances that are considered to require ‘priority’ have to be assessed first, taking into account the ECHA’s capacity to handle the authorisation applications.⁴⁹³ This “prioritisation” is orchestrated by the ECHA secretariat, which selects (according to a set of pre-defined criteria) the priority substances for inclusion in Annex XIV - the formal EU chemicals authorisation list.⁴⁹⁴ The national authorities are also engaged in the process through the Member State Committee.⁴⁹⁵ Based on an ECHA technical recommendation, the Commission then decides (via comitology) on the inclusion of these substances in Annex XIV, for authorisation.⁴⁹⁶ After a substance has been included in Annex XIV, applications for authorisation may be submitted by the manufacturer(s), importer(s), and/or downstream user(s) of the substance.⁴⁹⁷ The Commission is responsible for deciding on these applications, while the ECHA provides an expert advice on this.⁴⁹⁸ It does so through the Risk Assessment Committee (RAC) and the Socio-Economic Committee (SEAC), depending on the particular authorisation ‘route’ (as we shall see below).⁴⁹⁹

Importantly, this EU authorisation procedure is formally independent from the registration and evaluation processes. The subjection of a substance to authorisation does not require that it has

⁴⁸⁷ Supra 378, [REACH Regulation 2006], Article 60

⁴⁸⁸ *Ibidem*

⁴⁸⁹ *Ibidem*, Recital (78)

⁴⁹⁰ *Ibidem*, Article 59 (1)

⁴⁹¹ *Ibidem*, Article 59 (2) to (9)

⁴⁹² *Ibidem*, Article 59 (1)

⁴⁹³ *Ibidem*, Article 58 (3)

⁴⁹⁴ *Ibidem*

⁴⁹⁵ *Ibidem*

⁴⁹⁶ *Ibidem*, Article 60 (1)

⁴⁹⁷ *Ibidem*, Article 62 (2)

⁴⁹⁸ *Ibidem*, Articles 60 (1) and 64

⁴⁹⁹ *Ibidem*, Article 60 (2) and (4)

previously been registered or evaluated by the ECHA. This introduces a dimension of fluidity in the regulatory system. Whereas the ECHA explains that the “normal procedure” for the “identification” of a SVHC (i.e. the beginning of the authorisation procedure) is that “readily available sources such as registration dossiers and results from previous evaluation(s) are obtained and reviewed”, the ‘identification’ may still proceed without the registration of the substance if the required information is available.⁵⁰⁰ Different scenarios can therefore be envisioned. A substance may ‘only’ be registered and not yet evaluated and still be identified as a very high concern chemical. It is also possible that a substance has not even been registered but a SVHC dossier has already been prepared. What matters therefore is the information that is (or not) available and the different functions which these particular institutional layers occupy in the regulatory system.

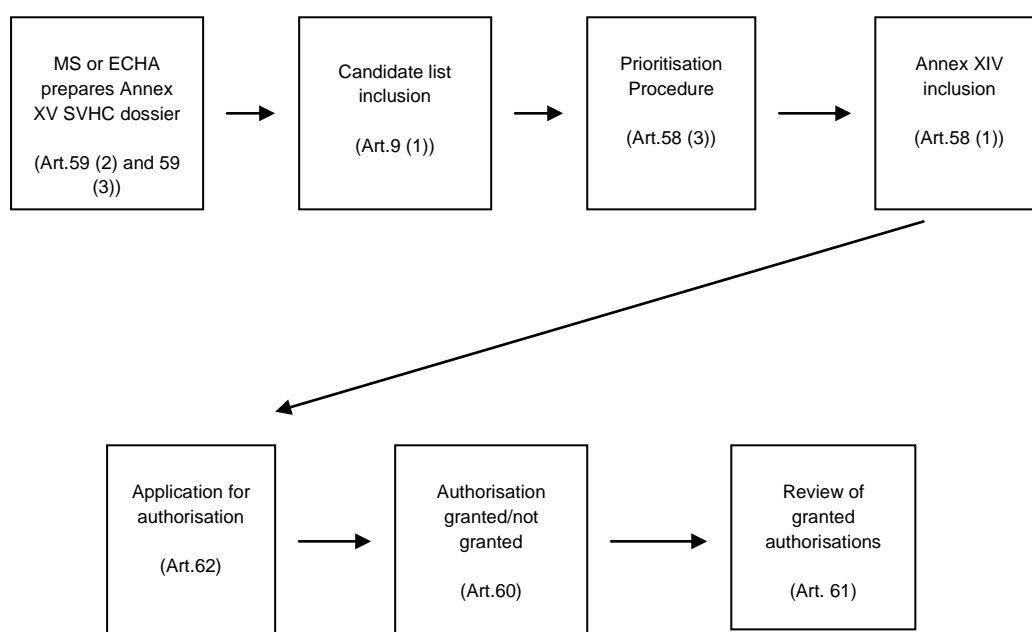


Figure 2: Simplified description of authorisation procedure⁵⁰¹

The importance of the substitution analysis and the socio-economic assessment

Once substances are included in Annex XIV (following the prioritisation process described above) they can be authorised either through the ‘adequate control’ route or via the ‘socio-economic’ route.⁵⁰² If the risks posed by a chemical are considered to be “adequately controlled”, an authorisation may be granted; but even if that is not the case, an authorisation can still be given if the socio-economic

⁵⁰⁰ European Chemicals Agency – ‘Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern’, guidance on the implementation of REACH, June 2007, p. 13

⁵⁰¹ European Chemicals Agency – ‘Guidance on the preparation of an application for authorisation’, guidance on the implementation of REACH, Version 1, January 2011, p. 3

⁵⁰² Supra 378, [REACH Regulation 2006], Article 60

benefits outweigh the risks and no safer alternatives are available.⁵⁰³ The discovery of alternatives is therefore a crucial part of the authorisation procedure, and so is the understanding of the socio-economic context of the substances. Whereas the preparation of a substitution plan (i.e. the commitment to substitute the substance under consideration by another one) is only required if the alternative is in fact safer and in case this substitution is technically and economically feasible for the applicant,⁵⁰⁴ every application for authorisation has to come with an analysis of alternatives.⁵⁰⁵ Even in the socio-economic route (which will only be considered if no substitutes are available) ECHA wants companies to invest in the research of potential substitutes and this will be taken into account when deciding the precise terms of the authorisation (e.g. length of the review period for the authorisation).⁵⁰⁶ On the other hand, while REACH does not require a socio-economic assessment (SEA) under the 'adequate control' authorisation route, the Agency recommends that every application includes that evaluation and (again) this can affect the precise terms of the authorisation (review periods, for example).⁵⁰⁷ This requires much from the industry, which has to invest significant resources in the identification of those socio-economic effects, communicate with the users and interested parties, and make its own case on the balancing of the chemicals' risks against the wider advantages associated with them.⁵⁰⁸ The key in a SEA is to "identify (and where possible quantify) the impacts that could occur under a refused authorisation in a proportionate and robust way."⁵⁰⁹ To that end, applicants have to define the so called "non-use" scenario (i.e. what would happen in case the authorisation is refused), and what would be the "likely response of relevant actors (manufacturers, downstream users, consumers, suppliers of alternatives, etc.)" if the substance becomes unavailable for a given use.⁵¹⁰ The socio-economic assessment requires applicants to assess sensitive and complex issues (e.g. employment concerns, relocations and trade-related matters, regional aspects).

The relevance of the substitution analysis as well as the growing status of the SEA suggests that the EU chemicals authorisation procedure represents much more than a 'yes or no' answer to the marketing of particular chemicals. It is better understood as a staged, complex and interactive process through which the EU regulatory system seeks to learn about the precise risks involved the use of chemicals that cause concern, force the investigation of safer alternatives by the industry and understand the socio-economic benefits of the said substances.⁵¹¹ Authorisation ensures an extensive analysis of risks and socio-economic benefits (from the applicants); but also the obligation of each manufacturer, importer and downstream user of the concerned substances to apply for an

⁵⁰³ *Ibidem*, Article 60 (4)

⁵⁰⁴ *Ibidem*, Article 62 (4) - (f)

⁵⁰⁵ *Ibidem*, Article 62 (4) - (e)

⁵⁰⁶ *Supra* 501, [Guidance on the preparation of an application for authorisation], p. 19

⁵⁰⁷ European Chemicals Agency, 'Guidance on the preparation of socio-economic analysis as part of an application for authorisation', guidance for the implementation of REACH, Version 1, January 2011, p. 10

⁵⁰⁸ *Supra* 378, [REACH Regulation 2006], Article 60 (4) – b

⁵⁰⁹ *Ibidem*

⁵¹⁰ *Ibidem*

⁵¹¹ *Ibidem*, Article 60 (4)

authorisation for their own uses.⁵¹² Considering the process of inclusion of a substance (Diarsenic Trioxide) in the EU authorisation list, the next section explains that this ‘learning’ potential of the EU authorisation procedure is being extensively relied on by ECHA to compensate for registration and internal capacity problems in the regulatory system.

Diarsenic Trioxide

Based on a dossier prepared by the French Competent Authority, Diarsenic Trioxide (DT) was identified as a Substance of Very High Concern (SVHC) as it is classified as a carcinogen (i.e. may provoke cancer) and it was then included in the candidate list for authorisation on October 2008.⁵¹³ DT is mainly used in Europe in the manufacture of glass, zinc by electrolysis and ultra-pure arsenic metal.⁵¹⁴ In the glass sector (where it has raised more concerns, as we shall see below), this substance is used (according to the ECHA) in the manufacturing process as a “decolourisation agent, enamel or a fining [removal of glass bubbles from the glass melt] agent.”⁵¹⁵ According to official estimates, the manufacturing volumes of diarsenic Trioxide within the EU are around 1,820 t/y.⁵¹⁶ The imported amounts are between 500 – 600 t/y (and those disposed of are about 200 t/y).⁵¹⁷ This means a total volume placed on the global market of 2,200 t/y.⁵¹⁸ As most of this volume (above 1,200 t/y) is exported to regions outside the European Union, the volume actually used within the EU is “in the range of 690 – 850 t/y [...]”⁵¹⁹ Concerning the glass manufacturing sector (which is the one that has raised more concerns, as we shall see below), the level of use of Diarsenic Trioxide in the EU is estimated at 150 t/y, and most of this “is used for the production of special glass”.⁵²⁰

The concerns of the ECHA with regards to Diarsenic Trioxide are thus essentially focused on the use of this substance in the manufacture of glass.⁵²¹ According to the industry, the glass sector “applies in general strict exposure restriction conditions as it uses several materials with CMR properties” and “due to the high toxicity of [Diarsenic Trioxide], the material is handled in industrial facilities under strictly controlled conditions (SCC).”⁵²² The ECHA notes, however, that regarding “occupational exposure, there seem to be problems with preventing such exposure in the manufacturing of hand-

⁵¹² *Ibidem*, Article 62

⁵¹³ European Chemicals Agency – Annex XV Dossier for Diarsenic Trioxide: Proposal for the identification of a substance as a CMR CAT 1 OR 2, PBT, vPvB or a substance of an equivalent level of concern, submitted by France on 20 June 2008, EC Number: 215-481-4, CAS Number: 1327-53-3

⁵¹⁴ European Chemicals Agency – ‘Background document for diarsenic trioxide: document developed in the context of ECHA’s second Recommendation for the inclusion of substances in Annex XIV’, December 2010, p. 2-3

⁵¹⁵ *Ibidem*, p. 4

⁵¹⁶ *Ibidem*, p. 2

⁵¹⁷ *Ibidem*

⁵¹⁸ *Ibidem*

⁵¹⁹ *Ibidem*

⁵²⁰ *Ibidem*, p. 4

⁵²¹ *Ibidem*, p. 11

⁵²² *Ibidem*

made decorative glass for arts and crafts [...]”⁵²³ According to the Agency: “[...] it is well recognized that different from the industrial glass sector, SCC is not guaranteed for the artisan handmade glass sector where supply of the material and mixing often occur under suboptimal conditions.”⁵²⁴ This evidence was obtained from studies conducted in the Murano district of Venice, which showed that the risks of lung cancer for those glass workers were higher than normal.⁵²⁵ Indeed, biological monitoring of those working in these glass manufactories (Murano) showed that “workers employed in the mixture preparation and in the furnace work are still significantly exposed to arsenic despite the technical preventive measures adopted.”⁵²⁶ In this Italian district, there are about 80 production sites and each of them employs around 800 – 1000 workers in the manufacturing of arsenic containing art glass.⁵²⁷ Also, in Murano, the annual consumption of As₂O₃ [molecular formula of DT] for art glass manufacture is about 8.2 t and 12 t/yr in the entire Italian territory.⁵²⁸ ECHA observes that whereas the industry (As-Consortium) “tried to find confirmation if practices in the artisan handmade glass making would lead to As₂O₃ exposure in other areas”, it still “could not find confirmation of such.”⁵²⁹ Unlike the Italian situation, the industry’s investigations show that in countries such as Austria or Belgium the artisan glass productions “seem either to use other substances for the fining and decolourisation in these types of crystal or have better controlled exposure management [...]”.⁵³⁰ Importantly, the National Competent Authorities (MSC) concluded that it is “**not clear**” whether occupational exposure to DT “**is a problem for the entire glass production industry or only of this specific part of it, i.e., artisanal glass production.**”⁵³¹ [Emphasis mine] In the light of these concerns, the Member State Committee decided (on December of 2010) to propose the prioritization of Diarsenic Trioxide for an EU authorisation.⁵³²

The Member State Committee discussions on Diarsenic Trioxide emphasise the fluidity of the EU regulatory system. The MSC had to decide whether or not to wait for the registration of the substance (which would have been available after 1 December 2010 at the earliest) before moving forward with further risk management measures.⁵³³ This (registration) information should then have allowed the MSC to better understand “the widespread use of the substance” and, hence, the real dimension of its risks.⁵³⁴ The committee considered, however, that the registration of DT would not generate the required information on its uses. The industry intended to register DT as an “intermediate” (i.e. a

⁵²³ *Ibidem*

⁵²⁴ *Ibidem*, p. 7

⁵²⁵ *Ibidem*, p. 6 - 8

⁵²⁶ *Ibidem*, p. 7

⁵²⁷ *Ibidem*

⁵²⁸ *Ibidem*

⁵²⁹ *Ibidem*

⁵³⁰ *Ibidem*

⁵³¹ *Ibidem*, p. 6-8

⁵³² European Chemicals Agency – ‘Opinion of the Member State Committee on the Draft Recommendation of the Priority Substances for Annex XIV Entries’, Adopted on 3 December 2010, ECHA/MSC-15/2010/029

⁵³³ *Ibidem*, p. 7

⁵³⁴ *Ibidem*

substance that is used in the manufacturing of another substance where it is itself transformed into that other substance); which would mean that only limited data would be submitted.⁵³⁵ For the ECHA, the use of DT in glass manufacture could not be classified as an intermediate as it is “not used in the synthesis of glass itself but as processing agent for modifying the properties of glass [...]”.⁵³⁶ The ECHA cannot, however, impose its views on this or force the future registrant to submit the dossier according to a particular understanding of the substance’s uses or its appropriate legal definition. This is a job for the industry. Moreover, this Diarsenic Trioxide episode appears to reflect a wider concern in the ECHA about the registrations. The Agency has noted that its “screening of over 400 registration dossiers for intermediates has indicated that 86% of them appear not to contain sufficient information to demonstrate that these conditions are fulfilled.”⁵³⁷ Companies are supplying less information than they are supposed to and there is not much that the ECHA is doing to control this.

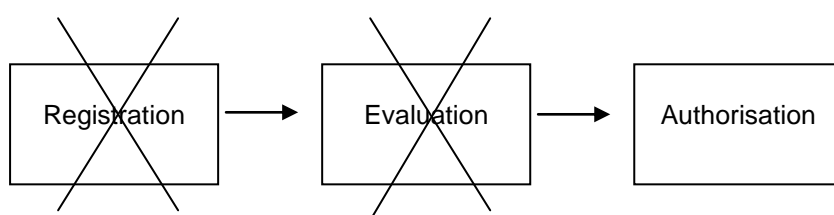


Figure 3: The operation of the REACH regulatory model in the case of Diarsenic Trioxide: this may happen in many other cases. While it does not represent an ‘abuse of power’ as such, the extensive use of authorisation for fact finding purposes forms an institutional anomaly, and it is problematic.

In contexts of uncertainty and internal capacity constraints, the use of the authorisation procedure has advantages for the ECHA.⁵³⁸ The Member State Committee’s conclusion that glass production problems in the Murano district “may occur in some similar sites throughout the EU” and that “there is no exposure data for the industrial glass production with the use of diarsenic trioxide” was therefore important.⁵³⁹ It was also noted by the Committee that an authorisation would “improve the conditions in the whole glass industry [...]”.⁵⁴⁰ This reasoning suggests that substances may be included in the EU authorisation list primarily as a way to get more information on their uses. The authorisation ‘path’ offers greater guarantees that the industry will not be able to hide behind incomplete registration dossiers.

While the institutional dynamics of Diarsenic Trioxide do not necessarily represent an ‘abuse of power’ as such, the extensive use of authorisation for fact finding purposes is an institutional anomaly (and it is not without problems). Authorisation can represent a significant burden for the industry (particularly for small and medium enterprises) and imposes regulatory obligations on third-parties

⁵³⁵ *Ibidem*

⁵³⁶ Supra 514, [Background document for diarsenic trioxide], p. 5

⁵³⁷ Supra 447, [Operation of REACH and CLP], p. 14

⁵³⁸ Supra 532, [Opinion of the MSC on the Priority Substances], p. 6-7

⁵³⁹ *Ibidem*, p. 7

⁵⁴⁰ *Ibidem*

(i.e. downstream users of the substances) which cannot be blamed for registration failures.⁵⁴¹ Perhaps more importantly, the reliance on EU authorisation to compensate for internal capacity constraints is inevitably limited in terms of its effectiveness and has its own problems. Registration involves thousands of companies and of substances. It is simply inconceivable that the EU authorisation procedure can grow enough so as to deal with most of the serious data gaps that remain in the system.

The limits of judicial controls

The inclusion of substances in the EU candidate list for authorisation has (we shall see below) led to litigation in the General Court and it is expected that the judiciary will also have to consider cases of Annex XIV inclusions (i.e. imposition of the EU authorisation requirement). However, judicial controls not only fail to constrain potential cases of public abuse, they are also incapable of solving any of the capacity problems which this EU regulatory system currently faces.

Following the entry into force of the Lisbon Treaty, it is now established that acts of agencies can be reviewed by the EU Courts if they are “intended to produce legal effects *vis-à-vis* third parties.”⁵⁴² The question is therefore what type of acts can be considered to “bring about a change” in the parties’ “legal position”.⁵⁴³ This question has emerged in the context of the ECHA candidate list entries. A number of chemical producers whose substances have been included in the candidate list are trying to challenge these decisions in the General Court.⁵⁴⁴ The EU Courts are adopting, however, a restrictive position that leaves these activities out of the control radar. While the General Court has not yet decided on the main proceedings of these cases, the President of this Court has already rejected a request for the interim suspension of ECHA’s decision to include a substance (Acrylamide) in the candidate list.⁵⁴⁵ In the case of Acrylamide, the applicant (SNF SAS), one of the world’s leading manufacturers of this substance, sought to suspend the ECHA’s inclusion of this chemical in the candidate list with the argument that this decision is causing considerable damage to its business.⁵⁴⁶ It contends that as a consequence of the identification of acrylamide as ‘very high concern’ (and its consequent inclusion in the candidate list), its customers are already anticipating a ban on the

⁵⁴¹ Supra 378, [REACH Regulation 2006], Articles 63 and 66

⁵⁴² Article 263 Treaty on the Functioning of the European Union

⁵⁴³ D. Chalmers et al., *European Union Law*, 2nd Edition, Cambridge University Press, 2010, p. 399

⁵⁴⁴ Case T-343/10 *Etimine and Etiproducs v ECHA*, Application (OJ) OJ C 288 from 23.10.2010, p.49; Case T-346/10 *Borax Europe v ECHA*, Application (OJ) OJ C 288 from 23.10.2010, p.51; Case T-268/10 *PPG and SNF v ECHA*, Application (OJ) OJ C 274 from 09.10.2010, p.23; Case T-93/10 *Bilbaina de Alquitranes and Others v ECHA*, Application (OJ) OJ C 113 of 01.05.2010, p.63; Case T-94/10 *Rütgers Germany and Others v ECHA*, Application (OJ) OJ C 113 of 01.05.2010, p.64; Case T-95/10 *Cindu Chemicals and Others v ECHA*, Application (OJ) OJ C 113 of 01.05.2010, p.65; Case T-1/10 *PPG and SNF v ECHA*, Application (OJ) OJ C 63 of 13.03.2010, p.48; Case T-542/08 *Evropaiki Dynamiki v ECHA*, Application (OJ) OJ C 44 of 21.02.2009, p.58

⁵⁴⁵ Case T-1/10 R (Order of the President of the General Court) *SNF v ECHA*, ECR 2010 Page II-00047*

⁵⁴⁶ *Ibidem*, paragraph 36

substance and will start using other alternatives instead.⁵⁴⁷ The Court disagreed with that assessment. Accordingly, the identification of acrylamide as a substance of very high concern “essentially does no more than confirm that it is potentially ‘hazardous’”.⁵⁴⁸ While the Court recognises that the aim of “authorisation” is the progressive replacement of very high concern substances for suitable substances and technologies, that is “far” from establishing “an absolute and unconditional objective of replacement”, and “makes the replacement envisaged dependent upon the economic and technical viability of those alternative substances and technologies” and on the evaluation of the socio-economic benefits of the substance.⁵⁴⁹

The Court’s assessment in the Acrylamide case also raises the question of whether it is possible to challenge Commission decisions including substances in the EU authorisation list (Annex XIV). Arguably, these acts are different from candidate list entries. They do not just confirm the dangerous properties of the substances (i.e. their “identification”) but already involve a stronger form of regulatory treatment. While the Order of the President of the General Court in ‘Acrylamide’ leaves some margin for interpretation, his reading suggests that judicial review of these decisions is difficult. The argument according to which the ECHA candidate list acts are not reviewable by the Courts because they do not force the substitution of the substances but depend on subsequent administrative assessments is also valid for the Annex XIV inclusions.⁵⁵⁰ For the Courts to control the (Commission) decisions which impose the EU authorisation requirement, the legal status of the ECHA technical opinions would also have to be addressed.⁵⁵¹ The EU Courts currently accept that the “formal legality” of agency opinions to the Commission can be controlled; but the fact that (here) the ECHA is only “preparing” the authorisations is relevant.⁵⁵² The General Court may still decide to strengthen the duties of justification on the Agency by requiring it to provide further reasons in support of its ‘Annex XIV’ technical proposals.

The public information on the ECHA’s Annex XIV opinions to the Commission is already extensive, however. More duties of justification on ECHA would only be useful if the level of uncertainty concerning the risks was not so high. The intervention of the EU Courts in this area would not appear to actually constrain possible instances of public abuse and it does not solve the internal capacity problems of the EU regulatory system. The ‘solution’ might have to be found in a reform of ECHA’s role and powers in the control of the industry registrations.

⁵⁴⁷ *Ibidem*, paragraph 53

⁵⁴⁸ *Ibidem*, paragraph 65

⁵⁴⁹ *Ibidem*, paragraph 55

⁵⁵⁰ *Supra* 545, [*SNF v ECHA*], paragraphs 55 and 56

⁵⁵¹ *Supra* 378, [REACH Regulation 2006], Article 58 (3)

⁵⁵² Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00, & T-141/00 *Artegoda GmbH and Others v Commission*, ECR 2002 Page II-04945

5- The need to reform the ECHA procedures: external capacities and fines

The deficits of the new EU chemicals policy have been a problem for ECHA and have an important impact on the dynamics of its internal processes. The current limitations of the registration system and the lack of capacity to control this through own resources generate a dysfunction in the way that procedures are used. There are also issues about (and limits to) the extent to which the system can support 'more authorisations'. This is hardly a standard option to deal with thousands of substances and with much uncertainty on their uses and risks. It is not coincidental that, according to the ECHA, the "growing workload of the [authorisation] Committees [...] is a cause for concern and the support for the members should be strengthened."⁵⁵³ It has also been observed that the Risk Assessment Committee "will face an unmanageable workload in the coming years" and that the magnitude of this work shall "depend especially upon the number of authorisation applications which are foreseen to reach a level of 200-400 annually in 2013-2014."⁵⁵⁴ In other words, there is a limit as to how much ECHA can do through 'authorisation' and those institutional processes should not be relied on too much for things that are not directly connected to the approval or rejection of the substances.

The reform of the ECHA procedures therefore has to take into account the promotion of a more effective policy and the maintenance of an internal structure that is predictable and which prevents institutional anomalies (such as the ones we currently find). Two dimensions of the regulatory model, in particular, should be reconsidered. The first concerns the relationship between internal resource constraints and the reliance on external capacities. The second deals with the enforcement of regulatory decisions and the controls on the industry. With respect to the first issue, ECHA could rely on environmental NGOs to serve as patrols and support the Agency in the review of the industry registration dossiers and the missing data. The new environmental patrols would not displace the basic authority of the Agency in the performance of those checks, but would inject more energy and capabilities in the regulatory system. Such collaboration could be organised by granting access to the data to the environmental group (or groups) and allowing them, at the end, to include (attach) an opinion on the relevant file and concerning the data that is possibly missing. One way to think about this partnership would be through the lens of regulatory "tripartism" (with some adaptations, as explained below).⁵⁵⁵ Tripartism is, according to its proponents: "a process in which relevant public interest groups (PIGs) become the fully fledged third player in the [regulatory] game."⁵⁵⁶ This approach empowers certain public interest groups (which have to show ability to perform the work and commitment to the objectives of the regulatory strategy) by giving them "access to all the information that is available to the regulator" and by involving the latter in the "real business of regulation".⁵⁵⁷ Tripartism was originally conceived in a context that is somewhat different to the one

⁵⁵³ Supra 447, [Operation of REACH and CLP], p. 64

⁵⁵⁴ *Ibidem*, p. 66

⁵⁵⁵ I. Ayres and J. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, 1992, p. 56

⁵⁵⁶ *Ibidem*

⁵⁵⁷ *Ibidem*, p. 57-58

considered here. It was promoted as a way to deal with the risk of ‘capture’.⁵⁵⁸ The idea, here, is not really to transform the environmental groups into a “fully-fledged third player” in the system, but to use them as patrols, to benefit from additional (external) capacity as a way to control information better and to identify problematic cases of industry non-compliance (with EU registration requirements). The selection of the particular environmental groups would also be based on an idea of “contestability”.⁵⁵⁹ Different environmental groups should compete for this policing role, which (hopefully) would also generate more interest in these positions and generate the appropriate capacity to perform the work.

Still, it is clear that use of external patrols will only be useful if the regulatory system is capable of ensuring that companies in fact supply more (quality) data on their substances. Additional resources, alone, might not solve the problem. One of the issues with the current model is that companies lack incentives to supply a full and complete description of their substances and of hazard profiles. The regulatory model needs to recognise this difficulty and tighten up the controls on the industry in what the provision of data is concerned. It is therefore suggested that the Commission be given the power to fine companies which have consistently and repeatedly failed to provide the data or shown lack of a credible effort to acquire that information and supply it to the Agency. The responsibility of the ECHA would be to make recommendations on fines, and the opinions of the environmental patrols should be attached to the relevant file. That should increase the pressure on the industry to fulfil its legal and regulatory obligations. The fines could, in addition, be expected to stabilise the internal processes of ECHA. It would become clearer that the authorisation procedure is only to be used if no other alternative can be found. Moreover, the Commission fines could be contested, judicially. On the basis of Article 263 TFEU, companies would be able to challenge these fines as they clearly interfere with their legal position.

In conclusion, one might borrow the terms of Harlow and Rawlings and say that this is an example of an area where we should give “green light” to the (European) public administration.⁵⁶⁰ Instead of conceiving the role of Law as that of establishing clear and fixed boundaries for governmental action or place all emphasis on the need to control the administrative activity of the state (the “red-light” perspective), the ‘green light’ view would accept that administrative law can be a “vehicle for political progress” and “welcomes the administrative state”.⁵⁶¹ Accordingly, the role of administrative law is not only to “stop bad administrative practice, and there might be better ways to achieve this than adjudication”; but to “enhance individual and collective liberty conceived in positive and not just negative terms.”⁵⁶² There are strong reasons to allow the ECHA to have the initiative on fines and to allow the Commission to impose them (where that is considered to be very much necessary). The poor policy of the EU in this area creates not only a problem in terms of its overall effectiveness; it is

⁵⁵⁸ *Ibidem*, p. 54

⁵⁵⁹ *Ibidem*

⁵⁶⁰ C. Harlow and R. Rawlings, *Law and Administration*, Cambridge University Press, 3rd edition, 2009, p. 37

⁵⁶¹ *Ibidem*, p. 31

⁵⁶² A. Tomkins, *In Defence of the Political Constitution*, *Oxford Journal of Legal Studies*, Vol. 22, No 1, 2002, p. 157

also problematic from the viewpoint of the institutional dysfunctions it generates (and the negative impacts which this implies for 'checks and balances').

Conclusion

The introduction of REACH promised big changes to the EU regulation of the sector. It predicted that through privatisation and centralisation strategies, more substance data would become available and that European public authorities would be better positioned to face the existing risks. But the registration of thousands of chemicals in the EU has proven to be very complicated, administratively, and has not generated the expected level (and quality of) data on the substances. ECHA also has a limited capacity to control these dynamics; it has few internal resources and is dependent on the industry for data provision. We have also seen that due to these problems, the regulatory procedures have become very unstable and favour the growth of the authorisation procedure as a fact finding device. The reform of the ECHA procedures is therefore important. It should recognise that the lack of effectiveness of a policy communicates strongly with poor 'checks and balances' in the system. Without a regulatory strategy that is effective (and internal capacity constraints are very challenging in this respect), the way in which the new administrative procedures will be used becomes more unpredictable and dysfunctional. The case for reform should consequently be supported on these two points: use of external capacities and the (Commission) power to fine companies (for serious and continuing failures to provide legal mandatory data). The proposed solution makes the best use of private interest groups and seeks to benefit from the resources and expertise which they might have for the benefit of the EU public interest. Moreover, the authority to fine companies would put pressure on the regulatory system to really justify well the use of the EU authorisation procedure. It stresses that authorisation is not to be relied on as a standard way of managing problems of access to the data, and (in such a way) the reform also contributes to the quality of the ECHA activities and to the stability of its internal procedures.

Chapter IV

The dualism of the ‘Lamfalussy’ model and the new institutional dynamics of EU securities regulation

Introduction

The year of 2001 marked an important turning point in the EU regulation of financial services. In July of the previous year the Council decided to nominate a “Committee of Wise Men”, headed by Alexandre Lamfalussy, to consider the difficulties facing the integration of EU securities markets.⁵⁶³ The final report of this committee argued that the absence of European-wide regulation on a number of issues, the inefficiency of the regulatory system and the inconsistent implementation of Community rules were standing in the way of the development of the European securities markets. This report was emphatic in its statement that the main impediment to progress in this area was related to the institutional system. The Wise Men’s point was that: “Whilst part of the problem concerns the incomplete regulatory coverage at European level, the greater part of the responsibility lies in the way in which EU legislation has been decided...and ‘implemented’...”⁵⁶⁴ After blaming the basic law-making process of the Union (i.e. Community method) for its slowness, rigidity and ambiguity in implementation; the Wise Men proposed that the EU financial regulation be handled through a new institutional structure. That model comprised three decision-making levels. Level 1 develops the “framework principles” of the legislation and this is agreed in accordance with traditional Community legislative procedures. Level 2 was concerned with the definition of “technical implementing measures”, adopted by the Commission under comitology (with the European Securities Committee).⁵⁶⁵ Importantly, the Lamfalussy model also introduced, at level 3, regulatory committees in the areas of securities, banking and insurance to adopt non-mandatory technical guidance implementing the level 1 and 2 rules. The three Lamfalussy committees were: the European Securities Regulators (CESR)⁵⁶⁶, the Committee of European Banking Supervisors (CEBS)⁵⁶⁷ and the Committee of European Insurance and Occupational Pensions Committee (CEIOPS).⁵⁶⁸ Finally, the enforcement of EU financial services law would be ensured by the Commission, at level 4.

This chapter considers the role of the CESR in the Lamfalussy structures. It studies, particular, this committee’s involvement in the development of two legal regimes of the Markets in Financial Instruments Directive (MiFID): the ‘best execution’ rules and the suitability and appropriateness.⁵⁶⁹

⁵⁶³ ‘Final Report of the Committee of Wise Men on the Regulation of European Securities Markets’, Brussels 15 February 2001

⁵⁶⁴ *Ibidem*, p. 13

⁵⁶⁵ Commission Decision 2004/8/EC establishing the European Securities Committee, *OJ L 3*, 7.1.2004

⁵⁶⁶ European Commission, Decision 2004/7/EC, *OJ L 3*, 7.1.2004, p. 32–32

⁵⁶⁷ European Commission, Decision 2004/5/EC, *OJ L 3*, 7.1.2004, p. 28–29

⁵⁶⁸ European Commission, Decision 2004/6/EC, *OJ L 3*, 7.1.2004, p. 30–31

⁵⁶⁹ Directive 2004/39/EC of the European Parliament and of the Council on markets in financial instruments, *OJ L 145*, 30.4.2004, p. 1–44

Whereas in ‘best execution’ level 3 (through a CESR ‘questions and answers’ document) played a central role in the definition of the new regulatory regime, and level 2/comitology was insignificant; the development of the suitability norms of MiFID were fully worked out at levels 1 and 2, with no space for CESR/level 3 to intervene. While in ‘suitability’ the EU political process occupied law-making territory in a way that made it more difficult for the regulatory structure to be of any use, in ‘best execution’ the instruments of CESR were found to be much better suited to engage with these dynamic and fluid markets. The ‘best execution’ experience suggests that one of the defining features of Lamfalussy was the link between the traditional political process of the Union and a new regulatory structure that allowed the EU to engage with a novel type of task, to integrate other types of actors and to promote particular instruments of public intervention in markets that are very dynamic and fluid. The Commission’s role changes in this context. While regulatory expertise grows into technical rule-making, the Commission becomes less of a rule-maker itself and more of a check on the new regulatory structures (although not necessarily a strong one, as we shall see). CESR was also highly constrained in terms of capacity, which created risks of capture by national expertise and emphasised its reliance on the sector in the course of its deliberative practices. The best ‘execution’ episode contrasts the importance of the wholesale interests in the CESR technical discussions with the marginalisation of the retail community in those instances. If this institutional imbalance is to be corrected, something ‘better’ than a one-off consultation with consumers might have to be offered.

After this research had been concluded, and following the global financial crisis of 2008, the institutional structures of EU financial regulation have been reformed. Among other things, CESR has been “reinforced” through the creation of the European Securities and Markets Authority (ESMA).⁵⁷⁰ We shall see below that in terms of rule-making, the new powers of ESMA to an important extent formalise the technical and institutional role of CESR in the Lamfalussy structures. While the significance of the reform should not be overstated, the ‘soft’ powers of CESR have given way to ‘binding technical standards’, which ESMA initiates, and the Commission has to approve. The growing connection between the EU financial regulatory state and the implementation of EU law requires that we pay more attention to internal constraints within the deliberative process of the EU regulator and to the existing risks.

I - The formal division of political and regulatory roles under the Lamfalussy model

The legislative distinction between ‘framework principles’ and ‘detailed implementing measures’ was one of the most important aspects of the Lamfalussy process. The difference between the two levels, however, has since the beginning been a source of ambiguity. According to a European Council resolution “the split between framework principles (Level 1) and implementing measures (Level 2) should be determined on a case-by-case basis in a clear and transparent way...”⁵⁷¹ The same

⁵⁷⁰ Regulation (EU) No. 1095/2010 of the European and the Council of 24 November 2010, *OJ L 331*, 15.12.2010, p. 84–119

⁵⁷¹ See: Y. Averignos, *Essential and Non-essential Measures: Delegation of Powers in EU Securities Regulation*, *European Law Journal*, Vol. 8, No. 2, 2002, p. 273

resolution also invites the Commission, when submitting its proposals, to indicate the kind of implementing measures it foresees.⁵⁷² The distinction between general orientations and detailed measures has therefore been a very fluid and uncertain one. For Avgerinos, the difference between the two levels “is more a political problem than a point of law.”⁵⁷³

The Committee of Wise Men’s report was not well received in the European Parliament. This institution was excluded from the adoption of technical implementation measures (level 2) and was only to be informed at that level.⁵⁷⁴ The creation of level 2 was seen as a way to transfer important regulatory functions to the Commission and the committee system, thereby compromising the EU inter-institutional balance.⁵⁷⁵ This uneasiness culminated when the Parliament massively approved a resolution which demanded a ‘call-back’ power over level 2 draft measures.⁵⁷⁶ The European Commission and the Council rejected this request, which “they perceived as a parliamentary intrusion in the broader comitology arrangements.”⁵⁷⁷ The Commission began, however, involving the Parliament in the level 2 discussions on an informal basis.⁵⁷⁸ In practice, this meant that the E.P. was given a period of one month to react to the proposals for technical implementing measures (level 2). The Commission pledged to take into account the opinion of the Parliament and, so as to improve transparency and the regular flow of information between the two institutions, Commissioner Bolkenstein proposed that “regular meetings” should take place.⁵⁷⁹

The inter-institutional tension was beginning to wound the workings of the Lamfalussy process. The EU institutions ended up agreeing on the introduction of a ‘sunset clause’ to the level 1 measures.⁵⁸⁰ A time constraint (four years) was then placed on the Commission to exercise delegated powers (level 2). As explained elsewhere: “the sunset clause was intended to provide reassurance that the Parliament’s demands for a change in the text of Article 202 EC would be addressed before the lapse of the initial four-year period of delegation.”⁵⁸¹ The change to the text of Article 202 EC was supposed to have taken place with the entry into force of the Constitutional Treaty. With its rejection, the problem still called for a resolution, which came in 2006, with the introduction of the ‘regulatory procedure with scrutiny’.⁵⁸² That new comitology procedure gave the Parliament a veto power over the exercise of delegated powers by the Commission.

⁵⁷² *Ibidem*

⁵⁷³ *Ibidem*

⁵⁷⁴ Supra 563, [Lamfalussy Report], p. 25-44

⁵⁷⁵ D. Chalmers et al., *European Union Law*, Cambridge University Press, 2006, p. 809

⁵⁷⁶ *Ibidem*, p. 810

⁵⁷⁷ *Ibidem*

⁵⁷⁸ Letter from Mr Bolkenstein, Member of the Commission, to Mrs Randzio-Plath, Chair of the Committee of Economic and Monetary Affairs, dated 2 October 2001

⁵⁷⁹ *Ibidem*

⁵⁸⁰ Supra 575, [D. Chalmers et al, 2006], p. 811

⁵⁸¹ *Ibidem*

⁵⁸² Council Decision 2006/512/EC, *OJ L 200/11*, 22.07.2006

CESR and level 3

In accordance with the Lamfalussy proposals, the European Union set up 'level 3' regulatory committees, which integrated the competent authorities of the Member States.⁵⁸³ The origins of CESR, in particular, could be found in the Forum of European Securities Commissions (FESCO), an informally established group which dates back to 1997. The competences of CESR were divided into two broad categories. The first consisted on the provision of technical advice to the European Commission at level 2. For Ferran, the "potential for CESR to dominate the Commission ... in the regulatory process is clearly present because CESR can draw upon its superior understanding of regulatory issues based on its members' day-to-day experience of grappling with the operation of financial markets."⁵⁸⁴ Secondly, CESR developed common standards of implementation and promoted regulatory and supervisory convergence (level 3). The CESR recommendations and standards did not have legal force. This Committee used peer review instruments to force its members to comply with the approved common positions. CESR was also a dynamic body that, over time, became more involved in the promotion of regulatory and supervisory convergence.⁵⁸⁵ According to Moloney, the "mismatch between CESR's formal status and the scale of its influence can ... be characterised in terms of its regulatory capacity or ability, as an expert network with an insecure formal foundation and with limited powers, to further regulatory goals or resolve problems."⁵⁸⁶

II – The reform of the Lamfalussy system and the establishment of ESMA

After the research on CESR that is presented here had been concluded much has happened in the global and EU financial world. Following the US subprime crisis (and once the global contagion effects of those problems had become apparent) the European Commission charged a High Level Group on Financial Supervision chaired by Jacques de Larosière to consider the case for reform of European regulation and supervision in the financial sector.⁵⁸⁷ This 2009 report goes beyond the organic architecture of EU financial regulation (it also addressed some substantive legal changes that were considered necessary); but the institutional dimension of that report's analysis and proposals is crucial. For the High Level Group, the old EU institutional design in this area failed to promote the required levels of legal and institutional cohesiveness and made it too difficult to respond to common challenges in a way that was credible, effective and quick.⁵⁸⁸ To be sure the problem was not just the level 3 committees. The Report notes that often it was the EU political process which failed to push for the desired level of harmonisation by leaving too much space for national options; which made

⁵⁸³ See: Commission Decision 2001/527/EC establishing the Committee of European Securities Regulators, *OJ L 191/43*, 13.07.2001, p. 43-44

⁵⁸⁴ E. Ferran, *Building an EU Securities Market*, Cambridge University Press, 2004, p. 102

⁵⁸⁵ See: N. Moloney, *Innovation and Risk in EC Financial Market Regulation: New Instruments of Financial Market Intervention and the Committee of European Securities Regulators*, *European Law Review*, Vol. 32, No 5, 2007, pp. 627-663

⁵⁸⁶ *Ibidem*

⁵⁸⁷ The High Level Group on Financial Supervision in the EU - Report, Brussels, 25 February 2009

⁵⁸⁸ *Ibidem*, p. 27

(according to the authors) the EU more vulnerable and less able to respond to the financial crisis.⁵⁸⁹ Moreover, the level 3 committees were limited in their ability to act in that they had few powers and could not manage all the problems at level 3.⁵⁹⁰ With regards to CESR, the High Level Group was particularly concerned with the absence of a legal mandate to adopt common decisions, the lack of resources of the committee, and an underlying problem of confidence between the national supervisors within this structure.⁵⁹¹

The de Larosière Report proposed instead to introduce a “European System of Financial Supervision” (ESFS) with strengthened level 3 committees. The ESFS is a network of EU financial supervisors that empowers level 3 while maintaining a decentralised structure in which the NCAs remain primarily responsible for the day-to-day supervision of their markets.⁵⁹² Having followed these proposals, the Union has equipped itself with three new structures that replace the former Lamfalussy committees: the European Securities and Markets Authority (ESMA), which replaces CESR;⁵⁹³ the European Banking Authority (EBA) (that supersedes CEBS);⁵⁹⁴ and the European Insurance and Occupational Pensions Authority (EIOPA), taking the place of CEIOPS.⁵⁹⁵ The de Larosière Report also concluded that, in order for them to be effective, the new financial services authorities should have more resources, “be able to employ more people, with a larger budget.”⁵⁹⁶ While this chapter is focused on CESR and on this tripartite decision-making model, the de Larosière Report also proposed changes in the EU system of macro-prudential supervision. Most notably, it proposed (and the EU has now established) a Systemic Risk Council in order to address systemic risks in the financial sector. The ESRC does not interfere with the (new) Lamfalussy “way” of doing things; but it gives Europe new instruments to assess and control the overall stability and integrity of the EU financial system as such.⁵⁹⁷

The structures of the reformed institutional system

The new institutional model maintains the four-level structure of the Lamfalussy procedure, but somewhat changes the formal role of ESMA at levels 2 and 3. The new level 2 reflects the distinction introduced by the Lisbon Treaty between delegated acts (Article 290 TFEU) and implementing acts (Article 291 TFEU). Regarding the delegated acts, the purpose of which is to substantiate the more general level 1 rules; the traditional (Lamfalussy) comitology system applies. The Parliament and the Council may object to these ‘regulatory technical standards’ or revoke the delegation of powers to the

⁵⁸⁹ *Ibidem*

⁵⁹⁰ *Ibidem*, p. 41-42

⁵⁹¹ *Ibidem*, p. 41

⁵⁹² *Ibidem*, p. 47

⁵⁹³ *Supra* 570, [ESMA Regulation 2010]

⁵⁹⁴ Regulation (EU) No. 1094/2010 of the European and the Council, *OJ L 331*, 15.12.2010, p. 48–83

⁵⁹⁵ Regulation (EU) No. 1093/2010 of the European and the Council, *OJ L 331*, 15.12.2010, p. 12–47

⁵⁹⁶ *Supra* 587, [de Larosière Report], p. 52

⁵⁹⁷ Regulation (EU) No. 1092/2010 of the European and the Council, *OJ L 331*, 15.12.2010, p. 1–11

Commission.⁵⁹⁸ This parliamentary ‘equivalence’ vis-à-vis the Council in the control of the Commission at level 2 was an important victory for the EP and it culminated years of inter-institutional struggle after the Lamfalussy procedure excluded the Parliament from the adoption of the implementing technical rules (see above). In this ‘first layer’ of the new level 2, ESMA may submit draft regulatory technical standards to the Commission for endorsement.⁵⁹⁹ Whereas the Commission may still decide not to follow ESMA’s recommendation, there is now an obligation of ‘reinforced cooperation’ between the Commission and the ESMA: the Commission (which has 3 months to decide whether to support the draft standards) cannot adopt the standards without justifying changes which it intends to make to the ESMA.⁶⁰⁰ If the Commission does not support the draft standards, ESMA has 6 weeks to revise them in the light of the Commission’s concerns and resend a revised version to this institution by means of a “formal opinion”.⁶⁰¹ As long as the ESMA complies with the relevant time limits for the amendment of the draft technical standards and has reworked them in a way that reflects the worries of the Commission, the latter cannot reject them or change them again without “prior coordination” with the ESMA.⁶⁰² When drafting binding technical standards ESMA also has to consult the (new) Securities and Markets Stakeholder Group, which means to ensure ‘balanced representation’ of “financial market participants operating in the Union, their employees’ representatives as well as consumers, users of financial services and representatives of SMEs.”⁶⁰³

Moreover, level 2 now includes a new category of acts (the ‘implementing technical standards’) which are governed by Article 291 TFEU and are adopted by means of implementing acts (Regulations or Decisions).⁶⁰⁴ These acts will be issued in areas specifically defined by the relevant legislative document and shall be of a ‘technical’ nature (they cannot imply “strategic decisions or policy choices” and should determine the conditions of application of the legislative acts).⁶⁰⁵ Institutionally, the main difference vis-à-vis the regulatory technical standards is that the Parliament and the Council do not control the exercise of these EU powers and only have to be kept informed throughout the process.⁶⁰⁶ The control of the implementing technical standards will be exercised by the Member States (since, post-Lisbon, this type of acts are not considered to be “delegated” by the Parliament/Council) via “comitology-style oversight procedures through the European Securities Committee.”⁶⁰⁷ In this layer of level 2, the task of the ESMA is to develop implementing technical standards and submit them as drafts to the Commission for endorsement.⁶⁰⁸ The relationship between the ESMA and the

⁵⁹⁸ Supra 570, [ESMA Regulation 2010], Articles 12 and 13

⁵⁹⁹ *Ibidem*, Article 10

⁶⁰⁰ *Ibidem*, Article 10 (1)

⁶⁰¹ *Ibidem*

⁶⁰² *Ibidem*

⁶⁰³ *Ibidem*, Article 37 (1) and (2)

⁶⁰⁴ *Ibidem*, Article 15

⁶⁰⁵ *Ibidem*, Article 15 (1)

⁶⁰⁶ *Ibidem*

⁶⁰⁷ N. Moloney, *The European Securities and Markets Authority and Institutional Design for EU Financial Market – A Tale of Two Competences: Part (1) Rule-Making*, European Business Organisation Law Review, Vol. 12, No. 1, 2011, p. 75

⁶⁰⁸ Supra 570, [ESMA Regulation 2010], Article 15 (1)

Commission is similar to the one that governs the adoption of regulatory technical standards: the ESMA may issue a formal opinion to the Commission in case of an initial disagreement; the Commission is not formally tied to that expert advice but before it changes the draft standards it has to “coordinate” with ESMA.⁶⁰⁹ The Commission ‘oversight’ of the binding technical standards might hide the existence of a shadow or covert delegation of powers to ESMA, where the Commission is formally in charge of technical rule-making but actually becomes more of an institutional check on the EU regulatory system.

At level 3, changes have also been introduced. Just like CESR did, ESMA may prepare guidelines and recommendations addressed to the NCAs or financial market participants in order to promote consistent supervisory practices in Europe.⁶¹⁰ Compliance with these documents is not mandatory but the peer review system has been reinforced through more formalised and demanding “comply or explain” procedures.⁶¹¹ The NCAs and market players have to “make every effort” to comply with the guidelines and recommendations.⁶¹² Once a guideline or recommendation has been issued, each NCA has 2 months to “confirm whether it complies or intends to comply with that guideline or recommendation”, and in case of non-compliance the relevant national authority has to inform the Authority and state its reasons.⁶¹³ ESMA then has to publish the fact that there was non-compliance by a competent authority, and may also decide (on a case by case basis) whether or not to “publish the reasons provided by the competent authority for not complying with that guideline or recommendation.”⁶¹⁴ In case it is required by the guideline or recommendation, financial market participants have to report “in a clear and detailed way” if they comply with that ESMA guidance.⁶¹⁵ Finally, ESMA is to inform the Commission, Parliament and the Council about the guidelines or recommendations which have been issued, state which competent authorities have failed to comply with them and how it intends to make sure that those authorities abide by its guidance in the future.⁶¹⁶ At level 3 ESMA has also been given further responsibilities in convergence of supervisory practices. As a consequence, ESMA may intervene in the mediation between NCAs;⁶¹⁷ and in the management of emergency situations.⁶¹⁸

⁶⁰⁹ *Ibidem*, Article 15 (3)

⁶¹⁰ *Ibidem*, Article 16

⁶¹¹ *Ibidem*, Article 16 (3)

⁶¹² *Ibidem*, Article 16 (3). The ESMA has to “publish” the fact that one or more national competent authority has not complied (or does not intend to comply) with the relevant guidelines or recommendation (Article 16-3). If it is required by the guideline/recommendation, financial market participants shall explain whether they comply with that instrument (Article 16-3). The ESMA then has to inform the Commission, EP and the Council which guidelines/recommendations have not been respected and which NCAs failed to comply (Article 16-4)

⁶¹³ *Ibidem*, Article 16 (3)

⁶¹⁴ *Ibidem*

⁶¹⁵ *Ibidem*

⁶¹⁶ *Ibidem*, Article 16 (4)

⁶¹⁷ *Ibidem*, Article 19. This may occur in two situations: in the settlement of disputes between the NCAs regarding the implementation of EU law (Articles 19 and 20); and in the supervision of the colleges of supervisors (Article 21). Regarding the first case, ESMA organises and sets a time limit for conciliation and if this breaks down, the Authority may adopt a binding decision requiring those national authorities to take a particular action or to refrain from doing something so as to settle the

Finally, at level 4 (and without prejudice to the general enforcement powers of the Commission under Article 258 TFEU) ESMA may investigate breaches of EU securities law and act upon the infringement, in cooperation with the Commission.⁶¹⁹ If a NCA has failed to comply with its EU legal obligations, ESMA may send a recommendation to the relevant NCA(s) setting out the measures necessary to comply with EU law.⁶²⁰ If the NCA has still not complied with the ESMA recommendation, the Commission may issue a formal opinion to that authority requiring compliance.⁶²¹ If the problem persists, ESMA may adopt an “individual decision” that is addressed to a financial market participant, demanding it to comply with EU law.⁶²² These individual decisions are only possible where the relevant EU legislative act itself (excluding an existing regulatory technical standard or an implementing technical standard) is “directly applicable to financial market participants”.⁶²³

(See next page)

conflict (Article 19 (2) and (3)). In what concerns the colleges of supervisors, which ESMA helps to coordinate (Article 21 (1)), the Authority may (in matters concerning systemic financial risks) or request particular deliberations of a college if a particular course of action which had been envisaged would disrespect EU law or harm the convergence of supervisory practices in Europe (Article 21 (2) – e)

⁶¹⁸ *Ibidem*, Article 18. ESMA may issue individual decisions in “emergency situations”, the identification of which has to be coordinated with the EU institutions (Article 18). Where the Council has identified the existence of an emergency scenario (as well as in in “exceptional circumstances” where coordination between the NCAs is necessary to ensure the integrity of financial markets or the stability of the financial system) the ESMA may adopt individual decisions that require the NCAs to take action in accordance with EU legislative acts (Article 18 (3)). In cases where the a (national) competent authority fails to comply with the decision of the ESMA, the latter may, where the applicable requirements laid down by EU legislation (including regulatory technical standards and implementing technical standards) are directly applicable to market actors, adopt an individual decision addressed to a financial market participant so as to require it to do what is necessary to comply with EU obligations (Article 18 (4))

⁶¹⁹ *Ibidem*, Article 17

⁶²⁰ *Ibidem*, Article 17 (2) and (3)

⁶²¹ *Ibidem*, Article 17 (4)

⁶²² *Ibidem*, Article 17 (6)

⁶²³ *Ibidem*

The Lamfalussy procedure

- 1- The EU legislator defines 'essential requirements'
- 2- Commission to adopt technical implementation measures under comitology (CESR advises)
- 3- CESR defines common standards of implementation (soft-law)
- 4- Commission checks Member State compliance

The reformed institutional system

- 1- The EU legislator defines 'essential requirements'
- 2- ESMA drafts regulatory and implementing standards and Commission adopts
- 3- ESMA adopts "comply or explain" guidelines and recommendations
- 4- ESMA and Commission enforce EU Law

The dynamics of the new institutional system

ESMA was established in January of 2011 and has done very little work so far. But while it is still early to make definitive statements on the impacts of the Authority, what we know from CESR may help us understand what is (and what is not) about to change. In the formal structures two main things have changed when compared to 'Lamfalussy': the creation of a new category of acts (the 'implementing technical standards'), and the reinforcement of level 3 through 'comply or explain' procedures. The new 'Lamfalussy' therefore creates an additional institutional layer between the former level 2 and level 3 where the standards developed by ESMA will be reflected in a Regulation or Decision. The 'de Larosière' reform announces an important formal shift in the system with the 'growth' of ESMA into level 2. It makes 'Lamfalussy' look more dualistic from an institutional standpoint by emphasising the distinction between the general political principles and orientations (which continue to be handled through the traditional law-making processes of the Union) and the development of more detailed 'binding technical standards', where ESMA has a prominent role. The Commission 'stays' at level 2 but its role also seems to be changing.

In many ways (and taking into account the research that is presented below), 'de Larosière' can be seen as formalising the institutional dynamics of Lamfalussy. Most of the problems which de Larosière identified in the previous structures (e.g. Directives too ambiguous, too detailed and purposely preserving national options) were connected to level 1 and nothing changes in the shape of that

central EU political dialogue. More importantly, the level 1 delegations to 'level 2 Lamfalussy' were not always as important as de Larosière makes them seem. We shall see below (when considering the drafting of the MiFID best execution regime) that one of the defining features of Lamfalussy was almost a full concentration of law-making at level 1 (with level 2 becoming a copy-out of the level 1 legislation) and the development of the required technical standards by CESR, at level 3. In this context, the formal role of the Commission has also been reassessed. In a 2011 FAQ, the ESMA interestingly notes that the role of the Commission (at level 2) is to "check that [the Authority's] draft laws are in the Union interest and are compatible with EU law and then to adopt these draft technical standards with minimal standards, if at all possible."⁶²⁴ This reading emphasises that while CESR/ESMA have grown into technical rule-making, the Commission 'remains' in the 'level 2' institutional system as a sort of Ombudsman, a source of institutional and procedural checks on the new EU regulatory expertise. The question as to whether this type of Commission oversight actually controls the dynamic institutional risks of ESMA will be answered in the negative.

The formalisation of ESMA's rule-making competences, the link between its internal deliberation and binding technical standards, is important. The Authority will now be able to use its 'implementing technical standards' to impose certain lines of action on the NCAs and financial market participants which otherwise would have to be dealt with at level 3, through soft guidelines. While these implementing standards formally co-exist with ESMA's level 3 guidelines and recommendations, what should matter is how actual problems should be addressed and fears of national non-compliance linked to level 3. To be sure, the formalisation of ESMA's authority does not imply that it will always be effective or successful in its endeavours (compliance problems may remain); but it somewhat reshapes 'level 3 Lamfalussy' and affects the terms of the relationship between the national competent authorities and between the latter and the regulated sector. The institutional system becomes less 'soft', less dependent on "peer reviews" to ensure EU compliance and more characterised by tighter mutual controls and stronger European commitments (which constrains the opportunities for underrepresented interests to go their own way).

Whereas 'de Larosière' proposed to increase the resources of the level 3 regulatory systems, ESMA is set to continue to rely on external expertise to a large extent. It is remarkable that while the budget of ESMA is €17 million for 2011 (it is predicted to grow to €24 million within a period of two years), the (UK) FSA annual budget for 2010-2011 was £458 million.⁶²⁵ The ESMA staff will "rise from 70 in 2011 to 120 in 2013", which is considerably more than what CESR had (and reflects the new competences of the Authority), but remains clearly insufficient to sustain the operational autonomy of new structure.⁶²⁶ The implication of these capacity constraints is that the EU regulatory system will remain very much dependent on external capacities. The national supervisors who provide the resources and engage more significantly with the technical discussions will therefore benefit, and so will the more

⁶²⁴ ESMA: 'FAQs: A Guide to Understanding ESMA', p. 4-5. See online: <http://www.esma.europa.eu/popup2.php?id=7366>

⁶²⁵ Supra 607, [Moloney, 2011], p. 81

⁶²⁶ *Ibidem*

influential wholesale interests which dominate the regulator's technical consultations. The new provision, requiring ESMA to consult a 'Stakeholders Group' (while preparing binding technical standards), falls below what could be expected to ensure institutional rebalancing in the context of the existing constraints. A bolder and more demanding system could involve ESMA having to explain in detail how its rule-making orientations communicate with the concerns expressed by consumers, representatives of the financial market participants' employees, users of financial services and SMEs (during consultation). While these internal controls may constrain the ESMA to a certain extent, they also emphasise the important role of this regulatory body in the governance of EU securities markets.

[First Case-Study]

III - The MiFID 'best execution' requirements

The Markets in Financial Instruments Directive (MiFID)⁶²⁷ was arguably the most important piece of legislation of the Financial Services Action Plan (FSAP).⁶²⁸ MiFID has the objective of liberalising and integrating the investment service industry in the European Union. The Directive maintains the "passport" principle of the Investment Services Directive (ISD)⁶²⁹ but provides for a much higher degree of harmonisation, in particular with regard to conduct of business rules. The ISD, approved in 1993, had major limitations from the point of view of the creation of an internal market in financial services, which were mainly related to the fact that firms continued to face significant costs when operating cross-border services. This happened mainly because the ISD did not prevent the Member States from applying their conduct-of-business rules on foreign firms. Although firms based on a Member State of the Union could use their operating licence as a "passport" to other jurisdictions, the effectiveness of such possibility was highly reduced by divergent legal, regulatory and supervisory frameworks. It is this limitation that MiFID fundamentally tries to overcome.

MiFID also aims to foster investor protection and promote competition in the provision of financial services. The abolition of the "concentration rules"⁶³⁰ should increase competition between established stock exchanges, Multilateral Trading Facilities (MTFs) and systematic internalisers (investment firms which internalise client orders on a systematic basis). Each of these regulated markets will now be able to trade shares in every Member State of the Union, putting an end to the monopoly that stock exchanges had in many of these countries. Secondly, the MiFID objective of enhancing the protection of investors relies mainly on four factors: 1) establishing rules relating to conflict of interest of investment firms; 2) the creation of a suitability and appropriateness regime which considers the investor's experience and knowledge; 3) forcing firms to achieve best execution for their clients when carrying out orders; and 4) introducing detailed rules on transparency and disclosure for share trading in regulated markets.

⁶²⁷ Supra 569, [MiFID level 1]

⁶²⁸ Communication from the Commission, Financial Services: Implementing the Framework for Financial Markets: Action Plan, COM(1999)232, 11.05.99

⁶²⁹ Council Directive 93/22/EEC, OJ L 141, 11/06/1993 P. 27-46

⁶³⁰ 'Concentration rules': provisions which require share trading to be executed in the established national stock exchange

This chapter focuses on the development of two particular regimes of the MiFID conduct of business framework. The first one is the 'best execution' regime. One of the key components of MiFID is the obligation of service providers to give clients the best possible result in their investments. This means that financial intermediaries who execute client orders have a clear obligation to act in their best interests. They have to execute trades in the regulated market which provides better financial results for the client. Best execution requirements are important because they not only set a standard of investor protection, but have the potential to determine the way brokers deal with market fragmentation and the choice among competing stock exchanges, multilateral trading facilities (MTFs) and systematic internalisers. After analysing the best execution experience, this chapter moves on to examine the development of the suitability and appropriateness rules. Suitability and appropriateness are tests which constrain the service that investment firms can provide to clients according to the characteristics of the latter. The objective of such regimes is to protect consumers of financial services from certain investments, the risks of which they cannot fully understand or be financially prepared to support. The rationale of these protections is the assumption that the relationship between a client and an investment firm is an unequal and unbalanced one, since the firm will normally understand the nature and risks of the services it provides more fully than the client (particularly if it is a retail client). In addition, the risks of a bad investment decision may harm the retail client considerably, while the investment firm is not faced with a comparable vulnerability.

1- The dual structure of the 'best execution' regime

The present section examines the development of the best execution rules. It concludes that the crucial moments in the definition of this regime were levels 1 and 3. The level 2 directive was little more than a 'copy-out' of MiFID level 1. The relevant matters left unaddressed by the implementing directive were relegated to CESR under level 3, where this body issued an important document: the 'Questions and Answers' on best execution.⁶³¹ Instead of a three-level process of decision-making, the Lamfalussy model displayed a dualist institutional dynamic. Levels 1 and 2 could be 'brought together' under the EU law-making umbrella; and that was then followed by the coordination of national implementation strategies at level 3.

The MiFID level 1 provision introducing best execution is Article 21. The best execution principle is prescribed in Article 21 (1) and provides the following:

Member states shall require that investment firms take all reasonable steps to obtain, when executing orders, the best possible result for their clients taking into account price, costs, likelihood of execution and settlement, size, nature or any other consideration relevant to the execution of the order.⁶³²

⁶³¹ The Committee of European Securities Regulators, *Best Execution- Questions and Answers*, Ref: CESR /07-320, May 2007

⁶³² *Supra* 569, [MiFID, Level 1 Directive]

Article 21 (2) then states that Member States shall require investment firms to set up an “order execution policy” aimed at establishing “effective arrangements to comply with paragraph 1.”⁶³³ The level of detail is considerably enhanced when the Directive considers the content of the order execution policy. Article 21 (3) is significant in this regard:

The order execution policy shall include, in respect of each class of instruments, information on the different venues where the investment firm executes its client orders and the factors affecting the choice of execution venue. It shall at least include those venues that enable the investment firm to obtain on a consistent basis the best possible result for the execution of client orders. (...) ⁶³⁴

When the best execution regime reached ‘level two’ the decision was to have an implementing directive⁶³⁵ which would not substantially develop the regime of Article 21 MiFID. The most significant example of this is the issue of ‘relative importance’ of execution factors. Article 21 (6)-(a) of MiFID level 1 states that, under level 2, the Commission shall adopt implementing measures concerning “the criteria for determining the relative importance of the different factors that, pursuant to paragraph 1, may be taken into account for determining the best possible result taking into account the size and type of order and the retail or professional nature of the client.”⁶³⁶ Article 44 (1) of the implementing directive then mentions the best execution criteria that investment firms have to take into account: a) characteristics of the client; b) characteristics of the client order; c) characteristics of the financial instruments subject of the order; and d) characteristics of the execution venues to which the order can be directed. However, when it comes to establishing the criteria for defining the relative importance of the execution factors, Article 46 (2)-(a) simply says that investment firms have to provide retail clients with the following details on their execution policy:

an account of the relative importance the investment firm assigns, in accordance with the criteria specified in Article 44(1), to the factors referred to in Article 21(1) of Directive 2004/39/EC, or the process by which the firm determines the relative importance of those factors.⁶³⁷

There is an important difference between the mandate provided by Article 21 and the extent to which MiFID level 2 defines the relative importance of the best execution factors. The implementing directive decides not to substantiate the best execution obligation and leave that task to the investment firm. The same regulatory constraint was evident in what concerns the inclusion of a list of the trading venues on the execution policy of firms. Article 46 (2)-(b) of the implementing directive basically repeats what the level 1 directive had already stated. The only issue where the level 2 directive increased the level of regulation of execution policies of firms was connected to client instructions [Article 46 (2)-(c)]. This provision prescribes that investment firms, through their execution policies, have to provide retail clients with a “clear and prominent warning” that any instructions from them may

⁶³³ *Ibidem*

⁶³⁴ *Ibidem*

⁶³⁵ Commission Directive 2006/73/EC, *OJ L 241, 2.9.2006, p. 26–58*

⁶³⁶ *Supra* 569, [MiFID Level 1]

⁶³⁷ *Supra* 635, [MiFID level 2]

“prevent the firm from taking the steps that it has designed” in its order execution policy to meet the best possible result.⁶³⁸

On the other hand, the level 3 story of best execution is radically different from the regulatory constraint displayed at level 2. In order to provide guidance on how best execution requirements should be implemented by the Member States; CESR chose a ‘Questions and Answers’ format.⁶³⁹ Unlike the level 2 directive, the Q&A did not fall short of substantiating the best execution obligation for investment firms. Put bluntly, the level 1 directive created the best execution principle and level 3 explained how to apply it. This is clear on the level 3 guidance on ‘relative importance’ of execution factors. Execution factors are the criteria which is used to measure how best execution is to be obtained and there were important discussions under level 3 to consider whether CESR should impose an obligation on firms to explain the relative importance of each of those factors. The Q&A document is quite explicit in this regard. It states that the execution policy should include the “key steps the firm is taking to comply with the overarching best execution requirement and how those steps enable the firm to obtain the best possible result.”⁶⁴⁰ This document also prescribes that the execution policy has to address the “... information on how those [execution] factors affect the firm’s choice of execution venues ...”⁶⁴¹ Without developing too rigid a method to measure best execution, the Q&A document still has considerable implications in terms of operational adjustments and costs for investment firms. Secondly, the Q&A bites on the nature of the relationship between investment firms and the stock exchanges in the fragmented and competitive European market that MiFID aimed to create. The best execution regime has the potential to determine the level of freedom that investment firms have to choose where to conduct share trading (see below).

The expertise and information of CESR in ‘best execution’ was therefore important. Defining a best execution obligation is an extremely complex process. It requires a good understanding of the processes through which firms execute share trading and the precise factors which matter to ensure that the investor is given the best financial treatment by the firm. The fact that these reforms are to be applied in 27 Member States is also relevant to understand why the regulators had the upper hand. A well-grounded knowledge of how firms, in the different European countries, provide investment services and products to their clients was important to ensure that the best execution rules to be introduced were adjusted to the functioning of markets. Moreover, the role of the national supervisors in the implementation of EU securities law emphasises an idea of institutional dependence. Approving ambitious directives, such as MiFID, may be seen as a significant step in the reform of financial markets in the European Union. The effectiveness of the proposed changes will ultimately depend on whether, and how, the Member States implement those changes in their national jurisdictions. The threat of sanctions in case of failure to implement by Member States may always be present, but in an

⁶³⁸ *Ibidem*

⁶³⁹ *Supra* 631, [CESR Q&A on best execution]

⁶⁴⁰ *Ibidem*, p. 6

⁶⁴¹ *Ibidem*

European Union of 27 Member States, and in a field as complex as the securities sector, one needs to be very optimistic to imagine the Commission going after each Member State that fails to implement some part of the 42 legislative measures of the Financial Services Action Plan (FSAP). The Commission understood that to ensure smooth and well-functioning processes of implementation it was important to embrace the national supervisors and CESR. The CESR's Himalaya Report is interesting in this regard, emphasising the important role of CESR members in the processes of national implementation.⁶⁴²

2- The nature of the dialogue within CESR and its risks

The central role of CESR in the definition of the best execution regime emphasises the importance of its internal deliberative practices. For the Commission, the main concern was that, within CESR, the national supervisors were essentially worried about their domestic firms (reflecting the lack of an EU dimension).⁶⁴³ In the words of a Commission official that had dealings with CESR, the main concern of the national authorities was that they "might get in trouble with their national firms".⁶⁴⁴ Also, the supervisors are accountable to their national governments and/or Parliaments. Their independence from national executives has not been uniform.⁶⁴⁵ CESR was also far from an ideal model of 'deliberative' decision-making. A Commission official who has often participated in CESR discussions explains that decisions were taken by consensus (no voting was held) and that in the beginning of the meetings "red lines" were clearly defined by the national supervisors.⁶⁴⁶ There was no sense of self-overcoming or common European vision. The same official also noted that the positions of the regulators "did not normally change during the negotiations."⁶⁴⁷

Moreover, the level and quality of national input in CESR was quite asymmetric. According to a former senior national official who was involved with CESR, the performance of the actual operational work of the Committee essentially rested on four Member States: the U.K, Germany, France and Italy.⁶⁴⁸ When the heads of all the national competent authorities would convene (in Paris, where CESR was based) the significant majority of them would only 'sit and watch', letting others do the talking.⁶⁴⁹ The active Member States, within CESR, did not just dominate the technical discussions; they also provided the resources for it to work. The internal resources of CESR were, in fact, quite limited. The CESR secretariat included not more than 20 people and only 4 or 5 really contributed to the technical

⁶⁴² The Committee of European Securities Regulators, 'The Role of CESR at "Level 3" under the Lamfalussy Process- Action Plan'. Ref: CESR/04-527b, 2004, p. 7

⁶⁴³ [Interview]: Respondent 1d (Commission)

⁶⁴⁴ *Ibidem*

⁶⁴⁵ [Interview]: Respondent 2d (CESR)

⁶⁴⁶ [Interview]: Respondent 1d (Commission)

⁶⁴⁷ [Interview]: Respondent 2d (CESR)

⁶⁴⁸ [Interview]: Respondent 3d (CESR)

⁶⁴⁹ [Interview]: Respondent 1d (Commission)

work of the Committee (the other were administrative staff).⁶⁵⁰ Inevitably, that gave an “advantage” to those countries which supplied the technical resources.⁶⁵¹

While the performance of the operational work of CESR rested on (voluntary) contributions from a few national competent authorities, the lack of resources of the Committee also emphasised the reliance on the particular expertise and dynamics of a sector that is highly complex and fluid. When the best execution rules reached level 3 important issues fell on CESR’s hands. There were significant tensions between: 1) Member States which were adapted to “internalisation” (executing the client’s order within the firm, see below) and those which were not; 2) bigger and smaller investment firms; or 3) investment firms and stock exchanges. In this context, we shall see that CESR tried to find a balance between the different interests involved; but that in doing that this conversation became essentially about articulating the tensions between the large investment firms and the stock exchanges. This is visible, first, in the clash between those interests in the so-called ‘prior express consent’. The question was whether a firm should obtain the prior express consent of its clients before executing orders outside a regulated market or a Multilateral Trading Facility (MTF). There was a conflict between the stock exchanges and investment firms because those wishing to internalise clients’ orders will have more or less difficulty in doing so depending on the nature and level of consent that has to be obtained from clients. This explains why Euronext, the ‘Deutsche Boerse’ and the London Stock Exchange were strongly in favour of making sure that firms seek “prior express consent” from clients before executing orders outside a regulated market or MTF. The majority of the views in the banking community were quite different. The British Banking Association, for example, made a strong case for a more flexible approach, arguing that in the case of the United Kingdom “the fact that a client has dealt with the firm for a period of time would be regarded as a “course of dealing” which could constitute consent.”⁶⁵² In its Q&A, CESR stated that internalisation of orders requires the prior consent of the client, but it also accepted that prior consent “may, at least in some jurisdictions, be tacit and result from the behaviour of the client such as the sending of an order to the firm after having received information on the firm’s execution policy.”⁶⁵³

The CESR Q&A reflected a concern with balance and coordination between the different market interests. More than forcing financial market participants to adjust to a particular vision of best execution, CESR tried to ‘build bridges’, to find solutions which communicated well with the views of the actors involved. However, the fact that an equilibria was found between those in the banking industry and the stock exchanges still raises the question whether those perspectives were really the only ones that mattered. The domination of the consultation process by the ‘large’ wholesale interests, as well as the importance of their input in the CESR Q&A, emphasises this difficulty. Only four

⁶⁵⁰ [Interview]: Respondent 3d (CESR)

⁶⁵¹ *Ibidem*

⁶⁵² Response from the British Bankers Association, p. 7; see: CESR Consultation Paper - Best execution under MIFID, Ref: 07-050b, 02.02.07

⁶⁵³ *Supra* 631, [CESR Q&A on best execution], p. 12

consumer groups participated in the best execution consultation.⁶⁵⁴ Moreover, there was no connection between the concerns expressed by the retail community on best execution and the duties of justification of the wholesale sector. The inter-institutional reports on the Lamfalussy procedure have also drawn attention to the lack of consumer input in these (level 3) dialogues.⁶⁵⁵

3- The role of the Commission and the CESR/ESMA duties of external justification

Under level 3 CESR is subject to few political controls. On the basis CESR's foundation decision, political control works through the Commission and the European Securities Committee.⁶⁵⁶ CESR is under an obligation to present its annual report to the Commission (Article 6) and should maintain close operational links with the Commission and the ESC.⁶⁵⁷ The best execution experience suggests that it is appropriate to focus on the nature of the relationship between the Commission and CESR at level 3. The 'questions and answers' on best execution are accompanied, in appendix, by a Commission working document where this institution submits "answers to CESR" on "scope issues" under MiFID and the implementing directive.⁶⁵⁸ It deals with three issues: 1) dealing on quotes; 2) use of specific instructions; and 3) obligations on portfolio managers and order receivers and transmitters. Without questioning the importance of such matters, the Commission document does not deal with some of the most controversial and sensitive topics on the level 3 best execution agenda (CESR did not demand answers from the Commission on such topics). These 'answers' to CESR on best execution (and the weaknesses of 'level 2 Lamfalussy', considered above) suggests that the Commission acquired an Ombudsman-type role in the operation of the system, it worked as a source of institutional checks on a regulatory committee that grew strongly into technical law-making territory. Meanwhile, those Commission controls (as seen in best execution) do not necessarily go to the 'heart' (or substance) of the relevant technical work, but may reflect particular concerns with process or specific matters that were called to the Commission's attention.

Following de Larosière, the Commission 'oversight' of EU regulatory expertise in this area has been formalised (see above). Where ESMA initiates binding technical standards, these will have to be approved by the Commission and the latter cannot adopt different standards without prior coordination with ESMA. Taking the CESR 'best execution' context as our reference point, we would then have the Commission "answers to CESR" (on best execution) possibly being channelled through the new level 2 procedures. The limits of the Commission/Ombudsman checks emphasise the importance of mechanisms of institutional rebalancing within the regulatory process itself.

⁶⁵⁴ Danish Shareholders Association, Euroshareholders, DECO - Portuguese Consumers Association and the Financial Services Consumer Panel Secretariat; see: CESR Consultation Paper - Best execution under MIFID, Ref: 07-050b, 02.02.07

⁶⁵⁵ See: Inter-institutional Monitoring Group, Final Report Monitoring the Lamfalussy Process, Brussels, October 2007, p. 4 and 11

⁶⁵⁶ Supra 565, [Commission Decision 2004/8/EC]

⁶⁵⁷ *Ibidem*

⁶⁵⁸ European Commission – Working Document ESC-07-2007, 'Commission answers to CESR scope issues under MiFID and the implementing directive', 19.03.2007

As explained above, the consultation of consumers in 'best execution' was poor, did not affect the relevant technical discussions and failed to generate any significant duties of justification from the large wholesale interests. ESMA now includes (as noted above) a Securities and Markets Stakeholder Group and the Regulation imposes mandatory consultation in the course of the Authority's rule-making processes.⁶⁵⁹ The creation of this structure emphasises the importance of the retail community in the reform of EU securities legislation. The stakeholder group seeks to restore institutional balance in the context of a sector that is dynamic and where the influence of the large wholesale lobby is considerable.⁶⁶⁰ But the ESMA markets and stakeholders group can also be seen as formalising the pre-existing CESR consultations, which were themselves part of the problem. Consultation does not sufficiently recognise the asymmetries of the market and the capacity constraints of the CESR/ESMA system. The important point is to restructure the terms of the internal dialogues within ESMA and strengthen the duties of justification of the Authority/sector vis-à-vis the underrepresented social and economic interests. Perhaps that objective could be better attained if ESMA was (in addition) asked to justify its draft technical standards in the light of the concerns expressed by stakeholders in consultation, creating a 'notice-and-comment' type of deliberative interaction. Even if the equal footing of the different interests can still not be ensured, the 'proceduralization' of external justification duties would hopefully strengthen the links between the various interests and promote the quality of EU rule-making.

[2nd Case-Study]

IV- MiFID's suitability and appropriateness rules

1- The legal framework of the suitability regime

After considering the CESR institutional experience in 'best execution', the focus now turns to the development of another important part of MiFID's conduct of business regime: the suitability and appropriateness rules. Suitability and appropriateness are tests which limit the access of the consumer to investment services according to the nature of the risk involved. The products or financial services the investment firms provide have to be "suitable" or "appropriate" to the client, having in regard her specific characteristics. The objective of such regimes is to protect the investors from investments risks which they cannot fully understand or be financially prepared to support. The suitability rules recognise that the relationship between a client and an investment firm is an unbalanced one. The firm will normally understand the nature and risks of the services it provides more fully than the client (particularly if it is a retail client). The firm is also not subject to a financial risk comparable to the one which is faced by a "normal" consumer of financial services. Beginning with an analysis of the relevant legal framework, this chapter shows that the detailed nature of MiFID level 1 and 2 pre-empted the development of guidance by CESR, at level 3.

⁶⁵⁹ Supra 570, [ESMA Regulation 2010], Article 37

⁶⁶⁰ Supra 607, [Moloney, 2011], p. 80

The suitability requirement is expressed in Article 19(4) MiFID.⁶⁶¹ This provision states that:

When providing investment advice or portfolio management the investment firm shall obtain the necessary information regarding the client's or potential client's knowledge and experience in the investment field relevant to the specific type of product or service, his financial situation and his investment objectives so as to enable the firm to recommend to the client or potential client the investment services and financial instruments which are suitable for him.⁶⁶²

Article 19(5) then creates a less demanding appropriateness test. This applies to investment services not covered by paragraph 4 (suitability). The appropriateness regime will normally apply to more general recommendations on a specific product. The nature of this test is different from the suitability requirement in three aspects: first, it merely places an obligation on the investment firm to "ask the client" to provide information, while the suitability test forces the firm to "obtain the necessary information".⁶⁶³ Secondly, paragraph 5 (appropriateness) is concerned with the client's "knowledge and experience" in the relevant investment field, while the suitability requirements are also focused on the client's financial situation and investment objectives. Thirdly, Article 19(5), unlike paragraph 4, explains the consequences of finding that the product or service is "not appropriate" to the client. In such cases the investment firm "shall warn the client or potential client", which can be done in a standardised format. Finally, Article 19(6), providing an exception, prescribes that under certain circumstances a firm may escape the obligation to obtain information from clients or meet the appropriateness tests when providing execution-only services and/or reception or transmission of client orders.

On the basis of MiFID level 1, the implementing directive develops a quite detailed suitability/appropriateness regime. It deals with suitability and appropriateness in three articles: Article 35 (assessment of suitability), Article 36 (assessment of appropriateness), and Article 37 (provisions common to the assessment of suitability or appropriateness).⁶⁶⁴ In what suitability is concerned, Article 35 imposes an obligation on Member States to ensure that investment firms obtain from clients (or potential clients) the necessary information to "have a reasonable basis for believing, giving due consideration to the nature and extent of the service provided, that the specific transaction to be recommended ..." is suitable for the client. The level 2 directive then reiterates the three conditions that MiFID level 1 had defined to measure this suitability requirement. The financial product or service should therefore: 1) meet the investment objectives of the client; 2) avoid financial risks which the client cannot bear, and 3) be such that the client has the necessary experience and knowledge in order to understand the risks involved.⁶⁶⁵

⁶⁶¹ Supra 569, [MiFID Level 1]

⁶⁶² *Ibidem*

⁶⁶³ *Ibidem*

⁶⁶⁴ Supra 635, [MiFID Level 2]

⁶⁶⁵ *Ibidem*

The second paragraph of Article 35 is of considerable importance, providing that professional clients can be assumed to have “the necessary level of experience and knowledge” in their relationship with the investment firm. The firm will only have to assess whether the product meets the investment objectives of the client and if the service it intends to provide does not create financial risks which are not consistent with the client’s investment objectives. In addition, for clients who are considered to be professionals (covered by Annex II to MiFID level 1 directive) the investment firm may assume that “the client is able financially to bear any related investment risks consistent with the investment objectives of that client.”⁶⁶⁶

The implementing directive goes on to substantiate, again with a considerable degree of detail, the information which firms need to obtain to assess the financial situation of the client (paragraph 3) as well as her investment objectives (paragraph 4). In specifying the information required to consider the financial situation of the client, Article 35 (3) prescribes that this shall include:

information on the source and extent of his regular income, his assets, including liquid assets, investments and real property, and his regular financial commitments.⁶⁶⁷

Another important issue that the directive deals with relates to the consequences of failure to obtain the necessary information from the client to assess the suitability of the product or service to be provided. The Commission directive is drastic in this respect, prescribing that: “Where, when providing the investment service of investment advice or portfolio management, an investment firm does not obtain the information required (...), the firm shall not recommend investment services or financial instruments to the client or potential client.”⁶⁶⁸ Article 36, on the other hand, is concerned with the assessment of appropriateness. Apart from repeating the content of Article 19(5) MiFID, it also creates an exception for professional clients, which may be assumed to have the “necessary experience and knowledge in order to understand the risks” involved in the investment services or products for which the client is classified as being professional.⁶⁶⁹ Article 37 then incorporates provisions common to the assessment of suitability and appropriateness. This provision explains which information is required to consider the knowledge and experience of retail clients. This information can be divided in three categories. The first one is the “types of service, transaction and financial instrument with which the client is familiar.”⁶⁷⁰ Secondly, the firm needs to consider the “nature, volume, and frequency of the client’s transactions in financial instruments and the period over which they have been carried out.”⁶⁷¹ Finally, the profession, relevant former profession and level of education of the client shall be taken into account.

⁶⁶⁶ *Ibidem*

⁶⁶⁷ *Ibidem*

⁶⁶⁸ *Ibidem*

⁶⁶⁹ *Ibidem*

⁶⁷⁰ *Ibidem*

⁶⁷¹ *Ibidem*

In conclusion, MiFID provided for a high level of harmonisation in this area and the level 2 directive was not just a copy-out of 'level 1'. The creation of a lighter regulatory regime for professional clients by the implementing directive clearly shows this. Having in mind the extensive nature of the suitability legislative framework it is unsurprising that CESR did not consider it necessary to define common standards of implementation for these rules.

2- The limits of level 3 and the nature of the 'suitability' risks

Having explained that EU law-making reduced the space for level 3 guidance, it is worth considering why this happened and what kind of challenges are associated with this. For the Commission (in what the suitability test is concerned) firms "need to know precisely what test they have to apply."⁶⁷² The idea seems to be that leaving things to level 3 would have resulted in regulatory confusion and lack of effectiveness. Moreover, level 3 was seen as 'weak' due to problems with the CESR "peer reviews" (which were considered not to put enough pressure on the national authorities to abide by the level 3 guidance). In the words of a national representative (CESR), the Committee's peer reviews "simply did not work".⁶⁷³ The Commission (and the Parliament) learned to somewhat distrust CESR due to these institutional failures.⁶⁷⁴

Secondly, the nature of the risk involved in the suitability tests helps to explain the heavy reliance on legal instruments in the development of that regime. Suitability and appropriateness requirements are designed to manage the access of investors to the market. They are associated with a more paternalistic and proactive conception of consumer protection.⁶⁷⁵ These tests were created to address a risk which is deemed to be serious enough to (possibly) justify a denial of the freedom to buy a financial product or service. This dimension of risk policy is important to understand why levels 1 and 2 were so detailed when defining the suitability regime. Unlike the suitability requirements, best execution rules were not established to address a great risk to investors. Best execution is essentially about making the consumer 'better off', forcing the investment firms to give clients the best possible result. A more flexible and loose regime in that context did not carry the same type of 'suitability' risks.

Thirdly, the nature of political conflict can prevent matters from being pushed 'downwards', towards CESR and level 3. The political tensions were visible at level 1: the European Parliament, in its first reading of MiFID, excluded suitability checks on execution-only services (services where the investment firm merely executes a client order, instead of providing investment advice or portfolio

⁶⁷² *Ibidem*

⁶⁷³ [Interview]: Respondent 3d (CESR)

⁶⁷⁴ Communication from the Commission of 20 November 2007 – "Review of the Lamfalussy process – Strengthening supervisory convergence", COM(2007) 727 final, p. 7-11

⁶⁷⁵ N. Moloney, *Building a Retail Culture Through Law: The 2004 Markets in Financial Instruments Directive*, European Business Organization Law Review, Vol. 6, No 3, 2005, p. 403

management).⁶⁷⁶ The view of the Economic and Monetary Affairs Committee of the Parliament reflected a concern with “light touch” regulation.⁶⁷⁷ The idea was that it was important to give meaning to investor choice, and avoid the introduction of an aggressive regulatory regime which unduly restricts the freedom of the consumer to evaluate what is appropriate for him. The Commission, on the other hand, seemed more concerned with making sure that the risks to consumer protection were effectively managed. Moreover, the different conceptions of consumer protection did not go away at level 2. A member of the European Parliament who was involved in the MiFID negotiations noted that issues where an institution ‘lost’ at level 1 could be re-opened at level 2.⁶⁷⁸ The suitability and appropriateness regime was no exception. When addressing the suitability issues, therefore, the level 2 process became politicised and prolonged the type of political interactions which had taken place at level 1.

3- Comparing ‘best execution’ and ‘suitability’: implications for CESR/ESMA

The analysis of these two MiFID regimes showed clear differences in the dynamics of the Lamfalussy procedure. In the best execution requirements, level 3 essentially ‘swallowed’ level 2. The EU political institutions defined the best execution principle and then CESR ‘explained’ – through its Q&A document – how that principle should be defined. On the other hand, the development of the suitability rules has been completely concentrated at levels 1 and 2. The nature of the risk involved in ‘suitability’ made it harder for these issues to be passed over to level 3. The existence of political differences between the Commission and the Parliament in the suitability agenda also worked as an ‘upwards’ institutional pressure and led to a more aggressive type of legal intervention.

The institutional contrast between the two MiFID regimes outlined above emphasises that ‘Lamfalussy’ generated a strong distinction between formal EU law-making and the emergence of a new regulatory system that was addressing novel challenges, engaging a wider range of actors and connecting with dynamic and transnational markets. This dualism had an important impact on the institutional role of the Commission. While the EU regulatory structures were growing into technical rule-making in some areas, the Commission started to check the operation of CESR. The notion that the Commission began to act a bit like an Ombudsman in this model underlines the significance of the institutional shift that was taking place here.

The de Larosière reforms have formalised these dynamics, as explained above. It has therefore become more important to see how the internal deliberative practices of ESMA work and what the risks are. The chapter also noted that the type of ‘politics’ which CESR advanced had some good things: the best execution experience suggested that CESR tried to secure mediation between

⁶⁷⁶ G. Ferrarini, *Contract Standards and the Markets in Financial Instruments Directive (MiFID): An Assessment of the Lamfalussy Regulatory Architecture*, European Review of Contract Law, Vol. 1, No 1, 2005, p. 36

⁶⁷⁷ *Ibidem*

⁶⁷⁸ [Interview]: Respondent 4d (European Parliament)

conflicting interests once issues got to level 3 and the committed way in which it connected with the sector allowed that to happen. Meanwhile, the conversations with the sector essentially involved the dominant wholesale interests: the global banks and the stock exchanges. Consumers, for example, were severely underrepresented during the technical discussions and the CESR Q&A was only concerned with how the best execution system was going to be organised between those wholesale actors. The absence of duties of external justification within the system vis-à-vis the retail community (wider interests) was problematic. Moreover, the way in which EU law has addressed this concern through de Larosière is unsatisfactory. The ESMA Regulation formalises the CESR consultations (through the creation of the Securities and Markets Stakeholder Group) without doing anything to rebalance the relevant institutional dialogues. Instead, ESMA could be asked to justify its rule-making initiatives in the light of the concerns expressed by stakeholders in consultation. A 'notice-and-comment' type of interaction would represent a bolder solution in an area where the internal capacity constraints of the EU regulatory system expose it to particular risks of institutional bias and capture.

Conclusion

The Lamfalussy process changed the EU financial services rule-making and regulatory dynamics in important ways. Lamfalussy maintained a three-level decision making structure, distinguishing between EU law-making, comitology and (what might be called) new EU regulatory forms of intervention. Its more interesting (and perhaps also salient) feature was, however, the emergence of a particular link between formal law-making (level 1 and level 2) and a regulatory system offering new capabilities and instruments in the management of complex, dynamic and fluid transnational markets. The role of the Commission changes, in that context. The Commission saw CESR grow significantly into technical rule-making, and that evolution has now been confirmed and formalised by 'de Larosière'. Whereas CESR's level 3 guidance was subject to few (formal) political constraints, the Commission is now more involved with the work of ESMA and has to approve the binding technical standards prepared by the latter. The Commission is not formally bound by the ESMA advice but has to justify changes to the draft standards. Moreover, the momentum of the system and the complexity of many of the technical issues which will have to be dealt with suggest the institutional role of the Commission at level 2 has been somewhat clarified; its potential as a 'check' on ESMA, a sort of Ombudsman in the new (level 2) institutional system, is being recognised.

CESR was (and ESMA is and will be) highly constrained in terms of regulatory capacity. The limited resources of the Authority create a risk of 'capture' by national expertise and emphasise its reliance on the dominant forces of a sector that is very dynamic and fluid. The prevalence of the large wholesale lobby in CESR's technical consultations (and the marginalisation of the retail interests) was problematic. By requiring ESMA to consult the (new) Securities and Markets Stakeholders Group in the course of technical rule-making initiatives, EU law runs the risk of formalising the institutional imbalances instead of counteracting them. A braver solution would involve stronger duties of external justification on the ESMA/sector collaboration and demand that the draft technical standards be

explained (internally) in the light of the concerns expressed by stakeholders during consultation. A commitment to pluralism in this area would also recognise the important and growing role of the 'regulatory state' in EU financial services.

Chapter V

External capacities and lenient regulatory checks: the European Aviation Safety Agency and its challenges

Introduction

The establishment of the European Aviation Safety Agency (EASA), in 2003, has been an important moment in the EU regulation of the sector.⁶⁷⁹ Most notably, the EASA is responsible for airworthiness type-certification of aircraft and parts in the EU. What the EASA does, in this context, is consider the airworthiness of the particular 'type' projects (e.g. Airbus A380 or Boeing 787) and it will issue a type-certificate where the relevant project meets the required safety and environmental standards. The granting of individual certificates to the aircraft, on the other hand, falls on the national aviation authorities (NAA). The EASA is also responsible for the continuing safety (airworthiness) of the approved aircraft and product types. In more recent years, the mandate of the EASA has been extended to cover the certification of flight crew licensing and the safety related aspects of air traffic management and air navigation systems. This type of work can broadly be understood as 'product-type' evaluation and licensing. We shall see, in this respect, that airworthiness type-certification (i.e. making sure that the aircraft types are safe) is what the EASA spends most of its time with, and the chapter is also focused on this. In addition, the EASA has also been given 'rule-making' responsibilities (i.e. provision of technical legislative advice to the EU institutions and issuing of 'certification specifications'),⁶⁸⁰ and it has moreover been handed the task of scrutinising the NAAs' compliance with EU legal requirements (this is called 'standardisation').

The creation of the EASA has therefore promoted the executive centralisation of type-certification tasks, something that is important in particular for the large EU manufacturing industry. European cooperation in the development of common certification codes for large aeroplanes and engines had previously been organised via the Joint Aviation Authorities (JAA), as we shall see below. But the EASA also takes on new responsibilities and has been given direct decision-making powers, namely to approve new aircraft models (types). The first years of the EASA were difficult. The Agency was forced to outsource all the type-certification work to the national authorities. Since then, EASA has progressively attempted (and to a certain extent also succeeded) to promote the internalisation of these tasks. Outsourcing to the NAAs continues to be important in this regulatory system, but now

⁶⁷⁹ Regulation (EC) No 1592/2002 of the European Parliament and of the Council, *OJ L 240*, 7.9.2002, p. 1–2. The new Basic Regulation governing the EASA is: Regulation (EC) No 216/2008 of the European Parliament and of the Council, *OJ L 79*, 19.3.2008, p. 1–49

⁶⁸⁰ Certification Specifications include 'airworthiness codes' and 'acceptable means of compliance'. Airworthiness codes are detailed technical rules which set the conditions of airworthiness that have to be met by aircraft types and products. Acceptable means of compliance is a form of EASA guidance which sets out the Agency's view on how the technical rules should be complied with

most or all of the (type-certification) work involving the large and more complex projects is performed in-house. A closer investigation into the type-certification procedures also shows, however, that in airworthiness type-certification the applicant company has crucial role in making the case for the safety of its 'product'. The reliance of the EASA on the external capacities of the industry is significant, and not without risks. There is a danger that the Agency ends up softening its controls on the industrial processes and that the required levels of safety of the products may be put at risk as a consequence. The chapter finds that the nature of this (EASA/applicant company) relationship has had a detrimental effect on 'checks and balances' in the institutional system. Whereas the EASA type-certification procedures provide for some internal controls via consultation with interested parties and through the intervention of the Panel of Experts (an internal structure created to review EASA deliberations) in matters which are considered to be 'important'; in practice those procedures are hardly used. The type-certification of the Airbus A380 will be used to show this dynamic in more detail. It is also found that the relevant decisions are taken between lower-level EASA experts (the product certification managers) and the applicant company, and that the checks on this work (through these EASA officials' hierarchical superiors) are quite rare.

The chapter is organised as follows: first, the role of the Joint Aviation Authorities is explored and the emergence of the EASA considered. Secondly, the chapter looks at the organisation of the EASA and investigates its regulatory mission. In the third section, the type-certification competences of the Agency are developed and the nature of EASA's regulatory capacity is assessed. Subsequently, the chapter explains the (nature of the) 'narrow' expertise of the EASA, its focus on a particular type of regulatory work. In the fifth section, the formal EASA procedures for airworthiness type-certification shall be examined. Finally, the chapter assesses the dynamics of deliberation within EASA and reflects on the challenges which this involves.

1- The Joint Aviation Authorities and the emergence of the EASA

In order to understand the motivations behind the establishment of the EASA, the nature and purpose of previous regulatory arrangements in Europe deserve to be considered. International cooperation in this sector has been important and it led to the Convention on International Civil Aviation (Chicago Convention), signed by 52 states on December 1944 (which defined minimum safety standards for civil aviation).⁶⁸¹ It was not until a few decades later that European countries agreed to build on these (international) minimum standards and work on further harmonisation of their aviation safety rules. This happened in 1970, when a number of European states created the Joint Aviation Authorities (JAA) in order to produce common certification codes for large aeroplanes and for engines.⁶⁸² Although these were soft rules, they set market expectations and were heavily relied on by the

⁶⁸¹ Convention on International Civil Aviation signed at Chicago on 7 December 1944. The Convention entered into force on 4 April 1947. It currently involves 190 Contracting States

⁶⁸² More specific information of the Joint Aviation Authorities is available online at:
<http://www.jaa.nl/introduction/introduction.html>

industry. In addition, the Joint Aviation Requirements (the airworthiness codes prepared by the JAA) became compulsory in the European Union with the approval of Council Regulation 3922/91.⁶⁸³ Member States were consequently under an obligation to accept products certified in accordance with these requirements, unless urgent “safety problems” required unilateral action, which would have to be duly justified.⁶⁸⁴ The restriction of the JAA to large aeroplane certification was considered to be important “to meet the needs of the European Industry and particularly for products manufactured by international consortia (e.g. Airbus).”⁶⁸⁵ Although the JAA’s mission was extended, in 1987, to all classes of aircraft, there is a very tight connection between the purpose and mission of the Joint Aviation Authorities and the perceived need to sort out the large aviation industry’s complications when it came to the certification of aircraft and parts on a EU-wide scale.

Despite a number of relevant achievements (outlined below), the JAA faced several institutional difficulties which sentenced its future. Schout explains that there had been “many delays in agreeing on rules implementing the JAA objectives, a lack of commitment from member countries towards the JAA’s non-binding legislation, industry being faced with many different national requirements, and unanimity voting preventing clear legislation and resulting in protracted decision-making.”⁶⁸⁶ The same author goes on to explain that, in the wake of the EU enlargement, the costs which the industry had to face to comply with nearly thirty different procedures were “enormous”, particularly for big aviation projects.⁶⁸⁷ The nature of the JAA’s decision-making process was therefore disappointing for the Commission, which wanted a “[...] strong and efficient agency able *inter alia* to carry out certification functions and to be a valid partner for foreign aeronautical authorities.”⁶⁸⁸ In conclusion, while the work of the JAA in the development of common aviation safety codes has been significant and the nature of its task central to the definition of the future EASA tasks in EU air transport safety, its incapacity to generate consensus in difficult issues and the absence of swifter standardisation processes opened the way for the creation of the European Aviation Safety Agency.

EASA

It was in the context of these institutional failures that the EASA’s focus on ‘type-certification’ began to be delineated. The solution would not be found in a reform of the JAA procedures, but instead involved the centralisation of certain executive functions. According to the system defined by Regulation (EC) 1592/2002, the granting of airworthiness and environmental type-certificates to

⁶⁸³ Council Regulation (EEC) No 3922/91, OJ L 373, 31/12/1991, p. 4-8

⁶⁸⁴ *Ibidem*, Article 8

⁶⁸⁵ See website page of the Joint Aviation Authorities: <http://www.jaa.nl/introduction/introduction.html>

⁶⁸⁶ A. Schout, *Inspecting Aviation Safety in the EU: EASA as an Administrative Innovation?*, p. 267; in Ellen Vos (ed.) *European Risk Governance: Its Science, its Inclusiveness and its Effectiveness*, CONNEX Report Series Nr 06, 2008

⁶⁸⁷ *Ibidem*, p. 268

⁶⁸⁸ European Commission, Proposal for a Regulation of the European Parliament and of the Council on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency, Brussels, 27.9.2000, COM(2000) 595 final 2000/0246 (COD). See explanatory memorandum, p. 4-5

aircraft and parts should be issued by the new European agency (EASA) directly and not by the national authorities, as before.⁶⁸⁹ Prior to an examination of the operation of these powers, the wider regulatory strategy of the EU and the significance of the new agency deserve to be considered. The notion that the first priority of the EASA should be centred on the certification of aircraft was clear in an important report on the future of EU aviation policy. This High-Level Group Report (2000), which formalised and represented the main political expression of the ‘Single European Sky’ (SES) program, launched in 1999 by former Transport Commissioner Loyola de Palacio, considered the main challenges faced by the EU in the field of air transport and opened the door to the establishment this agency.⁶⁹⁰ The assessment of the High-Level Group was that European competitiveness in the aviation sector was threatened by disparate and fragmented air traffic management (ATM) rules and by the absence of a coherent safety strategy.

Similar concerns were expressed by the Commission, in 2000, when this institution noted that the existing institutional system was “criticised for not being able to ensure aviation safety oversight efficiently and in a cost-effective manner”.⁶⁹¹ It was therefore hoped that the definition of common rules and the establishment of an “independent authority for the certification of aeronautical products would overcome those deficiencies.”⁶⁹² The Commission added that “thanks to a common system, applicants for certification of aeronautical products will have only one set of procedures to follow to get an approval, which would then be valid throughout the whole Community without restrictions or additional bureaucratic requirements.”⁶⁹³ This was considered “particularly important in view of the fact that Europe’s main competitors’ certification mechanisms, eg in the USA, are provided free of charge to the aircraft manufacturing industry.”⁶⁹⁴ The High Level Group supported the Commission’s views and argued that the “first priority” of this agency should be centred on aircraft certification.⁶⁹⁵ Moreover, the ‘Single European Sky’ (SES) underlined the importance of additional harmonisation efforts in the areas of air traffic management and air navigation systems (ATM/ANS). The fragmented nature of ATM/ANS systems in the EU was criticised by the Commission and by the High Level Group, which considered that these disparities caused increasing flight delays and significant economic inefficiencies. The SES approach therefore distinguished between “safety regulation” (where the EASA would become a central actor), and matters dealing with economic efficiency and air traffic management, which would not concern the new European agency.⁶⁹⁶

⁶⁸⁹ Supra 679, [Regulation (EC) No 1592/2002]

⁶⁹⁰ European Commission – Single European Sky, Report of the high-level group, Directorate General for Energy and Transport, November 2000. See: http://ec.europa.eu/transport/air/single_european_sky/doc/ses1_2000_hlgr_report_en.pdf

⁶⁹¹ Supra 688, [COM Proposal for EASA, 2000], p. 11

⁶⁹² *Ibidem*

⁶⁹³ *Ibidem*

⁶⁹⁴ *Ibidem*

⁶⁹⁵ Supra 690, [SES Report], p. 23

⁶⁹⁶ *Ibidem*, p. 15

2- The role of the European Aviation Safety Agency

EASA was established in 2003 and is based in Cologne.⁶⁹⁷ It is headed by an Executive Director (which is namely responsible for issuing the Agency's safety-related decisions) and is governed by a Management Board (which brings together representatives of every EU Member State and the Commission).⁶⁹⁸ The main tasks of the management board are in the definition of EASA's priorities, and it also monitors the performance of the Agency and establishes its budget.⁶⁹⁹ Moreover, as the EASA decisions have binding effects on third-parties (in type-certification matters, as we shall see below), the Agency also includes a Board of Appeal, the role of which is to check whether the decisions of the Executive Director correctly apply EU legislation in this area.⁷⁰⁰ Actions for the annulment of EASA acts, such as the ones covering type-certification, can only be brought before the European Courts after the appeals procedure has been exhausted.⁷⁰¹

In terms of its internal organisation of tasks, the EASA is divided into three main departments: the Certification Directorate, the Rulemaking Directorate and the Approvals and Standardisation Directorate. Indeed, the core of this agency's mandate covers these three areas (see below).

Type-Certification

As explained above, the 'first priority' of EASA has been airworthiness and environmental type-certification of aeronautical products, parts, and appliances (designed, manufactured or used in the EU). For the purpose of clarification, a type-certificate (e.g. the Airbus A380 or the Boeing 747 models) should be distinguished from the individual airworthiness certificates, which continues to be granted by the national authorities.⁷⁰² What the EASA approves is the general design model, the compatibility of those (design) characteristics with existing safety standards. The EASA also holds responsibility for 'continuing airworthiness', the ongoing scrutiny of the safety of the aircraft in order to assess whether or not the conditions upon which a type-certificate was issued are maintained. A certificate of airworthiness issued by the EASA remains valid as long as it is not suspended, revoked or terminated. Outside these exceptional circumstances, post-certification tasks include the approval of changes and repairs to the aircraft and components. An important regulatory instrument in this regard is the 'Airworthiness Directive': a document mandating certain actions to be performed on the aircraft so as to restore an acceptable level of safety, when evidence indicates that the safety of the aircraft can otherwise be compromised.⁷⁰³

⁶⁹⁷ Supra 679, [EASA Regulation 2008]

⁶⁹⁸ *Ibidem*, Articles 33 and 38

⁶⁹⁹ *Ibidem*, Articles 33 and 34

⁷⁰⁰ *Ibidem*, Article 40

⁷⁰¹ *Ibidem*, Article 50 (2)

⁷⁰² *Ibidem*, Article 5 (2) - c

⁷⁰³ Commission Regulation (EC) No 1702/2003, *OJ L 243*, 27.9.2003, p. 6–79; See Article 21A.3B (a)

The 'essential airworthiness requirements' have been defined by the Council and by the Parliament through the (EASA) Basic Regulation.⁷⁰⁴ These general requirements are then developed in the Commission implementing rules.⁷⁰⁵ The applicable airworthiness conditions for the issuing of type-certificates are defined in the Commission Regulation 'Part-21' (certification of aircraft and related products and parts).⁷⁰⁶ The implementing Commission norms leave the EASA, as the chapter explains further below, with a wide margin of technical discretion in the performance of its type-certification assessments.

- 1- The EU legislator defines the 'essential requirements'
- 2- Commission empowered to adopt implementing rules, via comitology (EASA advises)
- 3- EASA to issue type-certificates of aircraft and components
- 4- The Member States issue individual certificates to the aircraft

Figure 1: the institutional structure of EU regulation of aviation safety

Rulemaking

Under 'rulemaking', the Agency carries out two types of tasks. First, it advises the EU institutions in the context of any law-making activity which the latter may wish to pursue concerning safety regulation in the field of air transport. Secondly, the EASA issues certification specifications (airworthiness codes) and guidance material (acceptable means of compliance) for the application of EC law. These are not mandatory requirements, but represent the Agency's technical interpretation of EU legislation in this area. The influence of the Joint Aviation Authorities' work is visible in the airworthiness codes adopted by the EASA. The CS-25 (certification specifications for large aeroplanes), for example, essentially imported the JAR-25 (Joint Aviation Requirements for large aeroplanes) into the Agency system.⁷⁰⁷

The relationship between the Rulemaking and the Certification Directorates is a complex one. In fact, when the airworthiness codes have to be adapted or updated for particular projects because the relevant aircraft or parts involve novel design features, it is the Certification Directorate that develops and issues these 'special conditions'. That is an important part of the EASA's work (as we shall see below). On the other hand, if the airworthiness codes require general changes, and not simply special conditions for specific aviation projects, this task falls on the Rulemaking Directorate.

⁷⁰⁴ Supra 679, [EASA Regulation 2008]

⁷⁰⁵ Supra 703, [Commission implementing Regulation 2003]

⁷⁰⁶ *Ibidem*

⁷⁰⁷ European Aviation Safety Agency – Decision no. 2003/2/RM of the Executive Director of the Agency of 17 October 2003 on certification specifications, including airworthiness codes and acceptable means of compliance for large aeroplanes (« CS-25 »), ED Decision 2003/2/RM, Final, 17/10/2003

The rulemaking process of this agency recognises the importance of consultation opportunities. When a rulemaking initiative is started, be it for the provision of legal advice or for the purposes of developing certification specifications or acceptable means of compliance, the EASA publishes a 'Notice of Proposed Amendment' to inform stakeholders of its intentions and to give them a chance to submit their views.⁷⁰⁸ Following this discussion, the EASA prepares a 'Comment Response Document' which explains the official position of the Agency and how it communicates with the views expressed during consultation.⁷⁰⁹ Two consultative bodies support the EASA in the performance of its rulemaking tasks: the Safety Standards Consultative Committee (SSCC), where interested parties are represented, and the Advisory Group of National Authorities (AGNA). This chapter shall explain that, differently, the type-certification procedures allow for less consultation, foster more closed forms of deliberation, and place more emphasis on the authority of specific EASA experts in the management of the relevant "dossiers". According to an EASA official, this difference is inevitable because the "constraints" of both activities also differ; "certification operates on given projects with timelines"; and "design includes intellectual property rights so the level of openness is less than for rulemaking where discussions are more on general issues".⁷¹⁰

'Standardisation' (verifying national compliance)

The EASA is also concerned with the uniform implementation of EU aviation safety law in the Member States. This agency therefore assists the Commission in overseeing the effective application and correct interpretation of the legal requirements. Standardisation essentially involves the process of scrutinising the national authorities' compliance with the relevant rules. In order to do that, the Agency carries out inspections in the headquarters or regional offices of the national aviation authorities. The standardisation teams include at least one EASA member, who acts as team leader, and officials seconded from the national authorities. While EASA has to 'qualify' the NCA experts doing this standardisation work, reliance on national expertise in this exercise suggests that there is an element of 'peer review' in this. Moreover, the responsibility between the EASA and the national competent authorities in the aviation safety oversight is important. According to an EASA official, "99% of EASA inspections include a sampling of several approved undertakings, in order to monitor whether the NAA has properly discharged its certification and oversight duties."⁷¹¹ On the other hand, the more direct and local safety oversight responsibilities fall on the NAAs. With regards to this, an EASA official explains that it is "almost impractical for the Agency to perform ramp inspections on aircraft and aerodromes located in the territory" of a Member State; and that the NAAs "as competent authorities for certification and oversight of undertakings are responsible for oversight of those organisations that are on their territory except for Design Organisation Approvals" [DOAs are entities

⁷⁰⁸ For more details on the EASA's 'notice of proposed amendments', see website page of the Agency (Rulemaking Directorate) at: <http://easa.europa.eu/rulemaking/notices-of-proposed-amendment-NPA.php>

⁷⁰⁹ For more details on the EASA's 'comment response documents', see website page of the Agency (Rulemaking Directorate) at: <http://easa.europa.eu/rulemaking/comment-response-documents-CRDs-and-review-groups.php>

⁷¹⁰ [Interview]: Respondent 1c (EASA)

⁷¹¹ [Interview]: Respondent 2c (EASA)

considered to have the know-how required to design aviation products in accordance with the legal and technical rules and that are consequently granted certain privileges in the performance of such tasks].⁷¹² In conclusion: “EASA cannot perform ‘on-site’ safety oversight – but it can perform sample compliance checks at the undertakings’ level in the course of our [EASA] inspections, and that the EASA always does.”⁷¹³

The first extension of the EASA competences

When proposing the establishment of the EASA, the Commission explained that the Agency’s competences should, at a later stage, be extended to air operations and flight crew licensing, as well as to the regulation of the safety related aspects of airports, air navigation services and traffic management systems.⁷¹⁴ This view has been supported by Patrick Goudou, the EASA’s Executive Director, who has argued that the extension of the EASA system “to all aspects of aviation safety under a total system approach is technically consistent and logical.”⁷¹⁵ The reason for a gradual transfer of powers from the national authorities, under the JAA regime, to the EASA, can be explained by the significant regulatory challenges involved.

The first extension of the EASA competences has covered air operations, flight crew licensing and third-country authorisation. The European Union realised that the aviation community needed a uniform set of rules and a more efficient decision-making process not just for product certification, but also in what concerns air operations and flight crew licensing. Indeed, for a new aircraft type model to become operational, the competent authorities have to validate the airworthiness and environmental compatibility of that type design as well as the aircraft “operational qualification”, which includes the training and qualifications of crew members (cockpit and cabin), and operational suitability elements (e.g. procedures in cases of emergency).⁷¹⁶ And, therefore, through Regulation (EC) 216/2008, the remit of the Agency was finally extended to these areas.⁷¹⁷ The Commission implementing rules are expected by 2012 (meaning that this transfer of powers is not yet complete).

The 2008 Regulation also extended the mandate of the EASA to the authorisation of third-country operators. According to the Regulation, the EASA shall, in relation to third-country operators involved in commercial operations: a) conduct itself or through the NAAs (or qualified entities), investigations and audits; b) issue authorisations unless a Member State exercises the functions of the state of operator in relation to the relevant operators; and c) amend, limit, suspend or revoke these

⁷¹² [Interview]: Respondent 3c (EASA)

⁷¹³ *Ibidem*

⁷¹⁴ Supra 688, [COM proposal for EASA, 2000], Explanatory Memorandum, p. 5

⁷¹⁵ Speech by Patrick Goudou, Executive Director European Aviation Safety Agency, Conference on the Future of Aviation Regulation, Brussels, 20.9.2006, easa.europa.eu

⁷¹⁶ European Aviation Safety Agency – ‘OEB administrative guidance and procedure’, 01/11/2010, easa.europa.eu

⁷¹⁷ Supra 679, [EASA Regulation 2008]

authorisations if the conditions under which they were granted are no longer fulfilled.⁷¹⁸ These new tasks will impact on the updating procedures of the “Community List” of air carriers subject to an operating ban within the EU.⁷¹⁹ That list is defined by the Commission, assisted by a Committee of Member States. And while Regulation (EC) No 2111/2005 limited the role of the EASA to information reporting in what the Community list is concerned, its future competences in this field mean that if the Agency refuses third-country air carriers the relevant authorizations, it shall pass on to the Commission the information on which it based its actions. The EU should then consider whether the name of the air carrier should be included on that list.⁷²⁰

The second extension of EASA competences

Moreover, the competences of the EASA have been extended to cover aerodromes, air traffic management and air navigation systems. The “total safety approach system” outlined above, supported by the EASA and by the Commission, requires the Agency to grow into areas of airport and ATM/ANS safety. The ‘Single European Sky’ Group highlighted that the European aviation community would greatly benefit from increased coordination between the national ATM/ANC systems, the disparities among which cause increasing flight delays, harming economic efficiency and the environment.⁷²¹ While the new EASA tasks shall not become effective before 2012, according to Regulation (EC) No 1108/2009 (extending the mandate of the EASA to aerodromes, air traffic management and air navigation services) EU regulatory involvement in these fields is much weaker than in airworthiness type-certification.⁷²² National authorities shall (continue to) certify their own ATM/ANC systems.⁷²³ The EASA will benefit from certain certification tasks but in “clearly defined cases”, notably in external relations matters.⁷²⁴ Finally, one of the most significant aspects of this extension is the exclusion of airports (aerodromes, on the contrary, are covered) from this legislative package, the regulation of which is addressed separately in an “action plan” for airport capacity, efficiency and safety.⁷²⁵ In the opinion of an EASA official, this is an understandable solution and “there is merit in decentralisation in particular in the field of general aviation”; “proximity is important”.⁷²⁶

⁷¹⁸ *Ibidem*, Article 23 – 1 (a) (b) (c)

⁷¹⁹ Regulation (EC) No 2111/2005 of the European Parliament and of the Council, *OJ L 344*, 27.12.2005, p. 15–22

⁷²⁰ *Supra* 679, [EASA Regulation 2008], Recital (14)

⁷²¹ *Supra* 690, [SES Report]

⁷²² Regulation (EC) No 1108/2009 of the European Parliament and of the Council, *OJ L 309*, 24.11.2009, p. 51–70

⁷²³ European Commission – ‘Communication to the Council, the European Parliament, the European Economic and Social Committee of the Regions: Extending the tasks of the European Aviation Safety Agency - An agenda for 2010’, 15.11.2005, COM(2005) 578, p. 7

⁷²⁴ *Supra* 722, [Regulation (EC) No 1108/2009], Recital (12)

⁷²⁵ European Commission – Communication to the Council, the European Parliament, the European Economic and Social Committee of the Regions: An action plan for airport capacity, efficiency and safety in Europe, Brussels, 24.1.2007, COM(2006) 819 final

⁷²⁶ [Interview]: Respondent 1c (EASA)

3- EASA and airworthiness type-certification

The first years of the EASA were difficult. In 2003 and 2004 the Agency *delegated all the work* it was assigned to perform, through outsourcing contracts, to the National Aviation Authorities (acting under the responsibility and supervision of the European agency).⁷²⁷ As it became increasingly clear that the EASA was facing serious operational difficulties, the U.K. Commons Transport Committee, in 2006, considered this European agency to be “an accident waiting to happen” and it manifested concerns that the transfer of powers to this agency “could lead to a shift towards lowest common denominator and therefore the dilution of the CAA’s high standards of aviation safety.”⁷²⁸ The British Members of Parliament argued, in particular, that these operational shortcomings were creating a “knowledge gap” in the EASA and that this undermined safety innovation in this field.⁷²⁹ According to an EASA official, “we [EASA] don’t think this concern has materialised.”⁷³⁰ EASA began to progressively internalise the airworthiness type-certification tasks (see below). But some worrying figures remain, particularly concerning the continuing airworthiness (on-going safety oversight) targets. In 2007 the Agency was only able to perform 55% of the planned continuing airworthiness work.⁷³¹ Some progress was achieved in 2008, but still only 72% of the planned activities could be performed then.⁷³² An EASA senior official explains that this is a “critical issue” for this organisation and that the Agency continues to lack some resources in order to properly fulfil its mission.⁷³³

Partial internalisation

Faced with this troubled start, the EASA initiated an internalisation strategy which would require a significant increase of its staff numbers. In 2005, a total of 45 new Project Certification Managers joined the EASA.⁷³⁴ The Agency claims that by that year: “(...) all major transport aircraft and engine programmes, including related continuing airworthiness tasks, were already managed centrally from Cologne.”⁷³⁵ It has been reported that in many cases the Agency was “forced to internalise certification tasks at short notice” as the NAAs were losing their own staff.⁷³⁶ Despite these efforts, until 2006 this internalisation tendency only touched on 30% of the certification projects, affecting in priority the large projects.⁷³⁷ On the other hand, the EASA continued to rely, through outsourcing

⁷²⁷ European Aviation Safety Agency – 2006 Activity Report, (MB 04-2007), 30 May 2007, p. 20

⁷²⁸ House of Commons, Transport Committee: The Work of the Civil Aviation Authority, Thirteenth Report of Session 2005–06, p. 14 and 16

⁷²⁹ *Ibidem*, p. 17

⁷³⁰ [Interview]: Respondent 1c (EASA)

⁷³¹ European Aviation Safety Agency – 2007 Annual General Report, June 2008 (MB 02/2008), p. 12

⁷³² European Aviation Safety Agency – 2008 Annual General Report, June 2009 (MB 05-2009), p. 14

⁷³³ [Interview]: Respondent 4c (EASA)

⁷³⁴ European Aviation Safety Agency – 2005 Activity Report (MB 07-2006), p. 10

⁷³⁵ *Ibidem*, p.10-11

⁷³⁶ European Aviation Safety Agency – Multiannual Staff Policy Plan 2008-2010, Cologne, 28 March 2007, p. 35

⁷³⁷ *Ibidem*, p. 21

contracts, on the national authorities for smaller and less complex certification programmes.⁷³⁸ In the following years the centralising push of the EASA had a more significant impact. In 2007 the certification project work performed internally exceeded 50%, including all major projects and in 2008, after 145 additional temporary agent posts were occupied in the Certification Directorate, the Agency achieved a target of 63% in the level of internalisation for certification activities.⁷³⁹ This dynamic suggests that the national authorities remain a central part of the type-certification processes in the EU and that it is important to clarify the dividing lines between the ‘EASA product’ and the NAAs’ one, as well as the administrative impacts of this on the operation of the European agency. An example of the EASA’s retreating intentions, for less complex certification programmes, is the contract which it concluded with national regulatory authorities entrusting the latter with all activities related to gliders.⁷⁴⁰ According to the EASA this solution is justified by the fact that proximity is “important” in general aviation and “outsourcing does not mean transfer of responsibilities.”⁷⁴¹

The salience of new type-design activities in EASA

Despite the EASA’s type-certification limitations and transitional problems, the fact is that the Certification Directorate is the largest department of this organisation. According to 2008 figures, the Certification Directorate includes 34% of the EASA staff, followed by the Approvals and Standardisation Directorate (19%) and, finally, by the Rulemaking Directorate (14%).⁷⁴² These numbers would be more unbalanced (in favour of the Certification Directorate), had the Agency not decided to transfer to the standardisation department (inspections to the NAAs) a task which clearly concerns ‘certification’: the approval and oversight of design organisations (entities which are considered to design aircraft and parts in accordance with the applicable legal requirements).⁷⁴³ This internal rearrangement therefore hides that more than 50% of the EASA staff deal with certification tasks, whether it is product certification or design organisation approvals (considered below).

It is also significant that despite the EASA extensions, the prominence of new type-design (airworthiness) activities remains unaffected in the European regulatory framework. Based on recent indications, it appears that the level of resources directed towards the second extension areas (aerodromes and ATM/ANS systems) is quite limited. It is expected that these new activities will only require the EASA to hire, in 2011, one expert for the relevant certification activities. That is because “EASA has no certification responsibilities for aerodrome and only responsibilities for pan-European systems in ATM/ANS.”⁷⁴⁴ Until 2013, this number may rise to a total of 10 experts.⁷⁴⁵ This contrasts

⁷³⁸ *Ibidem*

⁷³⁹ *Supra* 732, [EASA Annual Report 2008], p. 12

⁷⁴⁰ European Aviation Safety Agency – Business Plan 2011-2015, December 2010, MB Decision 10-2010, p. 33

⁷⁴¹ [Interview]: Respondent 1c (EASA)

⁷⁴² *Supra* 732, [EASA Annual Report 2008], p. 67

⁷⁴³ European Aviation Safety Agency – 2006 Annual General Report, 30 May 2007 (EASA MB 04/2007), p. 2

⁷⁴⁴ [Interview]: Respondent 1c (EASA)

⁷⁴⁵ European Aviation Safety Agency – Business plan 2009-2013, MB 02-2009, January 2009, p. 20

with the 79 posts in the product certification department (2008), or with the allocation of 20 officials, during that same year, to the 'large aircraft section' (also product certification).⁷⁴⁶ Differently, the first extension areas (flight crew licensing and air operations) put more pressure on the EASA. This is particularly so in what concerns flight standards certification (operational suitability of the aircraft). Interestingly, even before the formal extension of the EASA competences had been accomplished, this organisation began providing, on a voluntary basis, certain services to the industry in this area of flight standards certification (maintenance review board activities).⁷⁴⁷ This highlights the importance of the EASA's role in the promotion of uniform and consistent safety standards for the introduction of new aircraft 'types'. Until 2013, the EASA estimates that 49 new recruits for flight standards certification will be in place.

While the level of regulatory work involved here is important, the figures show that, if one divides the product type-certification activities, distinguishing the *design* related activities from the approval of flight standards (operational suitability of the aircraft): the 'new type design' related tasks currently require more resources than what any new EASA powers will call for in the predictable future. The Agency estimates that until 2013, and for that year only, the number of hours performed in the area of flight standards certification does not exceed a total of 110.000.⁷⁴⁸ By contrast, in 2008 the EASA invested 122.681 hours in airworthiness and environmental certification and it estimates that this shall increase to a total of 152.986 hours in 2013.⁷⁴⁹ Finally, it is noteworthy that whereas in type-design certification the EASA has achieved a level of internalisation which exceeds the 60% mark, the Agency explains that in what concerns the first extension fields (FCL and air operations), its aim is to perform only 50% of the required work in-house, which means that outsourcing to the national authorities will have a deeper impact in these fields.⁷⁵⁰

4- The 'narrow' expertise of the EASA

The previous section highlighted that while the EASA has progressively developed a set of regulatory capacities to fulfil its mission; in reality the expertise on which it relies serves a quite specific type of task. This restriction has implications in terms of the nature (and origins of) the expert capabilities assembled in Cologne.

Looking at the distribution of nationalities in the EASA staff, it is striking that the number of French and German experts nearly equals the sum of all the other EU nationalities represented in this agency. In 2008, out of a total of 439 EASA agents, there were 111 Germans and 97 French.⁷⁵¹ For

⁷⁴⁶ Supra 736, [EASA multiannual staff policy plan 2008-2010], p. 21

⁷⁴⁷ Supra 745, [EASA Business plan 2009-2013], p. 25

⁷⁴⁸ *Ibidem*, p. 26

⁷⁴⁹ Supra 732, [EASA Annual Report 2008], p. 13. See also: European Aviation Safety Agency – Business plan 2009-2013, January 2009, p. 22

⁷⁵⁰ Supra 745, [EASA Business plan 2009-2013], p. 26

⁷⁵¹ Supra 732, [EASA Annual Report 2008], p. 67

an EASA member, “a predominance of nationals of the State where an agency is located is a commonly seen consequence of its business operation.”⁷⁵² Even if this was so (this level disproportion in the national origin of the experts is not common) one would still have to question why France is ‘represented’ in almost 1 out of 4 (EASA) officials. Another EASA official notes that “among all Member States Germany and France belong to the main aviation industry states which impacts on the quantity and quality of personnel trained in aviation.”⁷⁵³ Behind comes the United Kingdom with 43 officials and Italy with 34.⁷⁵⁴ Moreover, it is interesting, for example, that the two Product Certification Managers assigned to the Airbus A380 programme (Rachel Daeschler and Alexandre Peytouraux) are both French.⁷⁵⁵ An EASA member says that there is “no hidden intention here; we simply have used the people that had the knowledge because they were doing the same job in their country before the responsibility was transferred to EASA.”⁷⁵⁶

The EASA, as mentioned before, forms a system and not simply an agency with its own staff. The previous sections mentioned that the EASA has succeeded in internalising an increasing share of aircraft projects, but still today, in the field of airworthiness certification, more than 30% of all applications received by the Agency are contracted out to the national authorities. In what the outsourcing procedures are concerned, an accreditation procedure has been established by the EASA Standardisation Directorate to ensure that the national authorities have the required organisation and expertise to perform the relevant certification tasks.⁷⁵⁷ The initial accreditation requires on-site investigation and, in certain cases, may involve witnessing from EASA staff of a particular product certification project executed by the investigated entity (‘shadow certification’).⁷⁵⁸ Ongoing validity of the accreditation is subject to period assessments through surveillance programmes and there is a duty on the accredited entity to report any significant changes to the scope of accreditation.⁷⁵⁹ A total of 16 Member States (in addition to Switzerland and Norway) have been accredited by the EASA.⁷⁶⁰ More than 75% of the certification work performed by the NAAs on behalf of the EASA is carried out by five Member States: France, United Kingdom, Germany, The Netherlands and Italy.⁷⁶¹ These are, according to EASA, “also the countries where the vast majority of the design activities are located”, which means that they have “developed an expertise to discharge their responsibilities.”⁷⁶²

⁷⁵² [Interview]: Respondent 1c (EASA)

⁷⁵³ [Interview]: Respondent 5c (EASA)

⁷⁵⁴ Supra 732, [EASA Annual Report 2008], p. 56

⁷⁵⁵ See EASA online: <http://www.easa.eu.int/certification/consultations-comment-response-documents-CRD.php>

⁷⁵⁶ [Interview]: Respondent 1c (EASA)

⁷⁵⁷ European Aviation Safety Agency – Approval and Standardisation Directorate – Accreditation Procedure – S.P003-03 - 28/10/2008

⁷⁵⁸ *Ibidem*, p. 5

⁷⁵⁹ *Ibidem*

⁷⁶⁰ European Aviation Safety Agency – List of Accredited Entities, Ref. L001

⁷⁶¹ Supra 745, [EASA Business plan 2009-2013], p. 10

⁷⁶² [Interview]: Respondent 1c (EASA)

Equally significant is the possibility of NAAs being accredited to perform certification tasks in Member States other than their own. When the EASA came into operation the NAAs could only provide services to the EASA in relation to aviation products or parts if they were the “state of design”. Currently, however, a Management Board Decision allows national authorities to provide certification services in relation to products which were designed in other Member States if the state of design authority is not accredited or not able or willing to execute the task in accordance with the EASA procedures and within the required timeframe.⁷⁶³ An EASA official explains that the Agency has often made use of this possibility and that, for example, in the field of rotorcraft, a significant part of the relevant certification tasks are contracted out to Italy, which, according to the EASA, has acquired relevant expertise in this area.⁷⁶⁴

5- The formal EASA procedures for airworthiness type-certification

Having examined the wider impact of the EASA’s shrinking administration on the internal and external allocation of regulatory resources and on the type of ‘Europeanization’ involved here, it is important to consider the operation of the Agency’s type-certification procedures in order to consider the challenges associated with this specialised expertise.

The formal procedures shall be explained first. In the field of airworthiness certification, once an application is accepted, the EASA nominates a team of specialists to conduct the investigation of the relevant aviation product so as to assess whether it deserves to be granted an airworthiness type-certificate.⁷⁶⁵ These specialists are led by a Product Certification Manager (PCM) which is, along with his/her team, accountable to the responsible EASA Certification Manager.⁷⁶⁶ With the aim of establishing a ‘good’ certification team, the EASA Certification Manager may ask the applicant to provide an initial briefing for general familiarisation with the project.⁷⁶⁷ Following these exchanges, this official appoints a certification team and a Product Certification Manager to deal with the certification project. The EASA certification processes also include a Panel of Experts, formed by specialists with extensive technical knowledge in this field, which may be called on to provide advice on technical certification principles and on the interpretation of the implementing rules of the Basic Regulation.⁷⁶⁸

Once the team is finally established, the EASA type-certification procedures can be broadly divided in four stages: 1) technical familiarisation and establishment of the type-certification basis; 2) agreement of the certification programme; 3) compliance demonstrations; and 4) final report and granting of a

⁷⁶³ European Aviation Safety Agency – Decision of the Management Board on Guidelines for the Allocation of Certification Tasks to National Aviation Authorities and Qualified Entities – No. 04-2009 - Adopted at MB 01/2009 of 10 February 2009

⁷⁶⁴ [Interview]: Respondent 4c (EASA)

⁷⁶⁵ European Aviation Safety Agency – Type-Certification procedure, Doc # PR.TC.00001-002, Approval Date 09/07/2010, p. 8-9

⁷⁶⁶ *Ibidem*, p. 9

⁷⁶⁷ *Ibidem*, p. 10

⁷⁶⁸ *Ibidem*, p. 13

type certificate.⁷⁶⁹ It will be explained that most of the EASA's time, efforts and resources are directed towards the early certification stages (i.e. technical familiarisation and type-certification basis definition).

Technical familiarisation and type certification basis

During 'technical familiarisation' the EASA receives from the applicants "thorough technical briefings" about the product.⁷⁷⁰ This is important for the Agency to be in a position to "fully understand the design, including new used technologies and any unconventional features or unconventional usage of the product."⁷⁷¹ Normally, the applicable type-certification basis is defined at the end of the technical familiarisation stage, but in some cases this has been settled later on in the certification process.⁷⁷² The type-certification basis is formed by the applicable airworthiness code and the 'special conditions'.⁷⁷³ The airworthiness codes are more general standards and are "only amended when EASA gained sufficient experience with such technologies so that its contents are generic enough and not drafted around a technology (which would be the case of a special condition)."⁷⁷⁴ If, on the other hand, the particular design features of a product cannot be addressed by the applicable certification specifications (airworthiness codes) the EASA type-certification basis shall include these special conditions (and elect to comply).⁷⁷⁵ An aircraft which incorporates, for example, an innovative braking system, is likely to include special conditions addressing the relevant safety issues through specific engineering standards, adapted to that type of product and its specific characteristics. The special conditions therefore represent the more dynamic element of the type-certification exercise. The airworthiness provide for more general and stable standards on how the design of the products should be made, but this may need to be adapted if: 1) a programme includes novel or unusual features; 2) it involves unusual operations; or 3) service experience shows that unsafe conditions may be present.⁷⁷⁶ The initial type-certification basis is approved by the responsible EASA Certification Manager, and any changes made to this should be based on a draft prepared by the Product Certification Manager.⁷⁷⁷

Importantly, the decision-making process is different (and more open) when the special conditions are qualified as "important":

⁷⁶⁹ *Ibidem*, p. 10

⁷⁷⁰ *Ibidem*, p. 24

⁷⁷¹ *Ibidem*

⁷⁷² [Interview]: Respondent 6c (EASA)

⁷⁷³ *Supra* 703, [Commission 2003 Regulation, implementing measures], Part 21A.17

⁷⁷⁴ [Interview]: Respondent 1c (EASA)

⁷⁷⁵ *Ibidem*

⁷⁷⁶ *Supra* 703, [Commission 2003 Regulation, implementing measures], Part 21A.16B

⁷⁷⁷ *Supra* 765, [EASA Type-Certification procedures], p. 25-26

Deviations from the applicable airworthiness codes, environmental protection certification specifications and/or acceptable means of compliance with Part 21, as well as **important special conditions** and equivalent safety findings, shall be submitted to the **panel of experts** and be subject to a **public consultation** of at least 3 weeks, **except** if they have been **previously agreed** and published in the Official Publication of the Agency.⁷⁷⁸ [Emphasis mine]

The fact that when the special conditions are “important” they have to be subject to consultation and examined by the EASA Panel of Experts shows that there is a dual decision-making structure here (this is developed below when considering the type-certification of the Airbus A380).

The authority of the Product Certification Manager in the operation of the type-certification procedures is important. These procedures underline that: “[...] every effort should be made to resolve all kinds of disagreements concerning certification issues between EASA and the Certificate Holder/Applicant at the lowest possible level.”⁷⁷⁹ Therefore, the certification team forms the “primary decision-maker” in the process, acting under the supervision of the PCM.⁷⁸⁰ The certification team is given “the power to take the first decisions to the largest possible extent.”⁷⁸¹

Certification Programme

The agreement of the certification programme forms the second phase of the type-certification procedures. Emerging from a discussion between the EASA team and the applicant, the certification programme defines: a) the proposed means of compliance with the type-certification basis, and b) the activities and involvement of the EASA team in compliance demonstrations, test witnessing, compliance tracking and recording, conformity statements, and schedules for compliance to be achieved.⁷⁸² It is the applicant’s responsibility to produce this certification programme. This process is not a very transparent one. As these documents are owned by the companies and because the EASA does not publish information on the allocation of regulatory resources in particular projects, there is a lack of data on the Agency’s activities dealing, for example, with test witnessing.⁷⁸³ For an EASA member, this has to do with the fact that “certification deals with projects; projects include intellectual property rights.”⁷⁸⁴ Moreover, the same official says that EASA “consults on certain special conditions and this was not done in the past.”⁷⁸⁵ It is also noted that the US Federal Aviation Administration

⁷⁷⁸ European Aviation Safety Agency – Management Board Decision 7-2004 products certification procedure, 30 March 2004, (MB 02/04, 30 March 2004), Article 3 (2)

⁷⁷⁹ European Aviation Safety Agency – Management Board Decision 12-2007 amending the products certification procedure, 11 September 2007 (MB meeting 04-2007), Article 18(1)

⁷⁸⁰ *Ibidem*

⁷⁸¹ *Ibidem*

⁷⁸² *Ibidem*, Article 8

⁷⁸³ *Ibidem*

⁷⁸⁴ [Interview]: Respondent 1c (EASA)

⁷⁸⁵ *Ibidem*

“does consult on all special conditions but sometimes it becomes really repetitive.”⁷⁸⁶ Be it as it may, we shall see below (based on Airbus 380 type-certification process) that most of the EASA does not consult on most special conditions; which then means that the dialogue between EASA and the applicant company during the assessment of a type-certification project cannot be accessed or controlled through more open procedures.

Compliance demonstrations

Showing compliance with the certification basis is the applicant’s responsibility.⁷⁸⁷ The applicant should equally: a) define the EASA type design, b) produce a statement of conformity for certification tests, c) provide the required certification documents (compliance reports, manuals, etc.), and d) conclude the compliance reports with a Declaration of Compliance with the relevant requirements.⁷⁸⁸ These compliance demonstrations might then have to be accepted by the EASA certification team (depending on the design organisation approval privileges). The existence of DOAs (design organisation approvals) means that EASA will automatically accept some compliance documents submitted by the applicants. An EASA official notes that the DOA concept is “concept of the future” and that the Agency “is not in a position to verify all and everything done by the manufacturers on a given project.”⁷⁸⁹ Moreover, DOAs “are a way to ensure a demonstration of capability for design and logically some privileges should be given.”⁷⁹⁰ While the number of approved DOAs continues to grow, the Agency is progressively transferring the ones which still are managed by the national authorities to the European system. By the end of 2008, a total of 170 DOA were governed by the EASA and 74 remained with under national authorities’ supervision.⁷⁹¹ It is estimated that, in 2010, a total of 255 design organisation approvals had been issued by the EASA. This limits the EASA’s role to the early type-certification stages, concerned with the definition of the type-certification basis (airworthiness codes and ‘special conditions’). Moreover, while the EASA has the responsibility of scrutinising the DOA’s compliance with their legal requirements (by reviewing reports, inspections, flight test witnessing, etc.) the Agency appears to have some difficulties meeting these oversight duties (in 2008, for example, only 54% of the planned audits to DOAs were performed).⁷⁹²

Final Report and Type-Certificate

The fourth and final stage of the type-certification process consists of a Final Report and the granting of a type-certificate. Once the relevant milestones of the certification programme have been achieved, the applicant offers a declaration of compliance stating that the type design of the aircraft complies

⁷⁸⁶ *Ibidem*

⁷⁸⁷ *Supra* 779, [EASA MB Decision 12/07], Article 8

⁷⁸⁸ *Ibidem*

⁷⁸⁹ [Interview]: Respondent 1c (EASA)

⁷⁹⁰ *Ibidem*

⁷⁹¹ *Supra* 732, [EASA 2008 Annual Report], p. 18

⁷⁹² *Ibidem*, p. 15

with the applicable EASA type certification basis.⁷⁹³ This should be followed by a statement of satisfaction of the team members to the PCM. The latter shall then issue a compliance statement to the responsible EASA Certification Manager, confirming that the type design of the product respects the type certification basis.⁷⁹⁴ The type-certificate is granted by the Executive Director of the Agency.

6- The dynamics of deliberation: the challenges and the controls

Having examined the formal EASA procedures for airworthiness type-certification, the chapter seeks to better understand how these work and what kind of issues emerge from those dynamics. As some of the previous paragraphs already noted, the transparency of these processes is a challenge. While (here) we are dealing with industrial projects with intellectual property rights, it can also be important (as we shall see) for the sector and stakeholders to check how the technologies of a given project are being handled and how the EASA is developing its mission, more generally. We will see below that the problem of transparency is mainly linked to the number of special conditions which are classified as 'important' (as that generates a more open decision-making system) and that, in practice, most of the decisions escape those procedures.

Secondly, the formal steps outlined above also suggest that the applicant company has a crucial role and is mainly responsible for the type-certification process. The certification programme, in particular, is prepared and owned by the applicant company. One of the effects of this is that it is virtually impossible to check what the exact role of the EASA in the certification processes really is (as the companies will not supply this information to the general public).⁷⁹⁵ As a consequence, with the exception of a few facts which are sometimes made public (which is usually the case in very large and symbolic type-certification projects where the public will be informed that, for example, EASA pilots were involved in the test flights of a particular new aircraft model that is undergoing type-certification analysis);⁷⁹⁶ 'nobody' knows what the EASA is (or not) doing in the course of particular type-certification programmes.

While it is not ignored that the EASA has to operate in the context of certain institutional constraints connected to the nature of these industrial projects, it is nevertheless questionable that everything (or almost everything) should be secret or decided without prior consultation. In this regard, the type-certification 'special conditions' are important. When a given type-certification project incorporates new technologies the safety of which cannot be addressed through the existing airworthiness codes,

⁷⁹³ Supra 779, [EASA MB Decision 12/07], Article 11

⁷⁹⁴ *Ibidem*

⁷⁹⁵ I have tried to get hold of this information (with respect to the Airbus 'A380' project, considered below) but was unsuccessful. The EASA re-directs us to the company for data on the certification programme, and the latter is not normally willing to share this material, which contains confidential information

⁷⁹⁶ See: Airbus: 'Airbus A380 receives joint EASA & FAA Type Certification', 12 December 2006. See online: <http://www.airbus.com/newsevents/news-events-single/detail/airbus-a380-receives-joint-easa-faa-type-certification/>

the EASA has to draft special conditions, representing new safety standards that manage the novel design features. These 'special conditions' consequently form a new and very specific form of EU industrial checks. They are relevant also in that they stabilise market expectations (through the creation of new standards), which may guide the concerned industry and serve as the basis for future regulatory updates (through the amendment of the airworthiness codes).⁷⁹⁷ We shall see below that while the drafting of these special conditions is meant to integrate a wider range of actors in the decision-making process and generate certain 'checks and balances' in the process; that rarely happens in reality.

The reduction of consultation opportunities: looking at the A380 project

The type-certification of the Airbus A380 is the 'flagship' of the EASA. The A380 is the largest commercial airliner in the world, with capacity for 555 passengers.⁷⁹⁸ This aircraft has been presented as one of the most significant technological breakthroughs in the global aviation industry (not only for its significant capacity but also for the efficiency and environmental standards which it has set).⁷⁹⁹ After decades of planning and several years of tests (accumulating more than 2,600 flight test hours), the Airbus A380 received its EASA type-certification on December of 2006.⁸⁰⁰

The dynamics of EASA deliberation in the case of the A380 type-certification suggest that the operation of these procedures is challenging in terms of who is involved and how the regulatory expertise may be checked. To begin with, EASA appears to manage airworthiness type-certification through a heavy reliance on lower-level officials (the product certification manager) and his/her decisions are rarely reviewed by the hierarchical superiors (certification manager and director). In the Airbus A380 certification programme, there was (only) one issue where the product certification manager and the Airbus experts failed to agree on, motivating the intervention of the Certification Director.⁸⁰¹ The fact that most decisions are often kept at a 'low' technical level appears to indicate that the expertise of some of these officials is not matched by others in the EASA; and without expert substitutes 'peer reviews' cannot really take place.

It was explained above that in the context of EASA airworthiness type-certification the only issues which may be accessed by the public are the 'important' special conditions. Everything else is settled between the EASA experts and the applicant company 'behind closed doors'. Moreover, the case of the Airbus A380 shows that in practice most special conditions are classified as 'normal' (i.e. not important) and as a consequence they are not subject to consultation nor have to be examined by the Panel of Experts. In the A380 type-certification process, only three special conditions were considered

⁷⁹⁷ Supra 703, [Commission Regulation 2003, implementing measures], Part 21A.16B - Special Conditions

⁷⁹⁸ G. Norris and M. Wagner, *Airbus A380: Superjumbo of the 21st Century*, Zenith Press, 2005, p. 158

⁷⁹⁹ *Ibidem*

⁸⁰⁰ Supra 796, [Airbus A380 receives joint EASA & FAA Type Certification]

⁸⁰¹ [Interview]: Respondent 7c (EASA)

to be “important” and consequently subject to consultation and to the Panel of Experts’ review; the remaining 39 special conditions fell under the “normal” category, meaning that, here, the Product Certification Manager only needed to coordinate with the company.⁸⁰² Taking into account the many and significant product design innovations introduced by this new aircraft ‘type’, the limited number of special conditions classified as “important” in the A380 type-certification process suggests that most of the relevant matters were “previously agreed” (as the type-certification procedures call it) between the PCM and the Airbus experts, therefore escaping the more open and inclusive processes which the ‘important special conditions’ call for. As mentioned above, in the US the FAA consults on all special conditions.

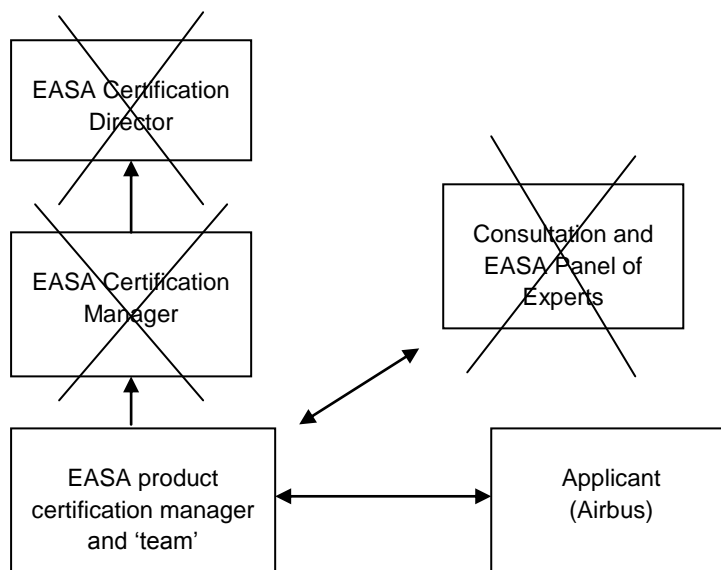


Figure 2: the dynamics of deliberation in the Airbus ‘A380’ type-certification process. The important decisions were taken between the EASA product certification manager and the applicant company, with very few (hierarchical) institutional checks and almost no stakeholder consultations (or intervention of the Panel of Experts)

The consultation on the three A380 ‘important’ special conditions also stresses that these dialogues are confined to a very limited number of actors. Only Boeing and the UK regulator (the latter only on one occasion) were interested in commenting on the A380 “important” special conditions. Boeing’s concerns dealt essentially with the US manufacturer’s worries that harmonisation in these specific fields might not be achieved through these special conditions, calling for technical refinements to the

⁸⁰² European Aviation Safety Agency – ‘Type-Certificate Data Sheet for Airbus A380’ - No A.110, 28 September 2011, p. 1-16 (see below for more details on the A380 special conditions):
 Comment-Response Document for Airbus A380, SC D-43
 See online: <http://www.easa.eu.int/certification/docs/crd/CRD%20D-43.pdf>
 Comment-Response Document for Airbus A380 - SC D-39
 See online: <http://easa.europa.eu/certification/docs/crd/CRD%20D-39.pdf>
 Comment response document for Airbus A380 D04 – Crew Rest Compartment
 See online: <http://easa.europa.eu/certification/docs/crd/CRD%20CRI%20D-04.pdf>

standards so that harmonisation with the existing (US) Federal Aviation Administration rules may be better achieved.⁸⁰³ Considering the very complex and technical matters that are being addressed here it is hardly surprising the process does not invite many comments. Perhaps this may also suggest that other safety issues in the A380 were perhaps more important or interesting for the industry or stakeholders but these did not undergo the more open process of the important special conditions.

Conclusion

The operation of the European Aviation Safety Agency highlights that this body relies to an important extent on the capacities of the regulated industry, and the nature of this interaction raises questions about how checks and balances within the system can be maintained and promoted. We have seen that the first years of the EASA were very challenging, operationally (the Agency essentially had to outsource all the type-certification work to the national authorities). EASA then began a progressive move in the direction of 'internalisation' of these tasks and it appears to have been modestly successful in doing so. When one digs deeper into the type-certification procedures and into the Agency's more precise responsibilities, however, it also becomes clearer that most of the work in this area is performed by the applicant company (with the Agency serving as a sort of check on industrial self-regulation). There is a risk, here, of having the EASA becoming too uncritical of the industry's assessments, too close to its processes or lacking the ability to understand where the problems are.

One of the concerns which these institutional dynamics raise is that 'checks and balances' may be difficult to ensure under the particular constraints of the industrial activity considered here. While the EASA type-certification procedures 'recognise' that the important relationship in this system is really between the Agency's experts (product certification managers) and the applicant's 'people', those procedures also allow for some consultation and internal reviews via hierarchical superiors of the product managers (as well as through the Panel of Experts). In practice, however, the decision-making space is much more reduced, consultation rarely occurs and the Panel of Experts has become marginalised. To be sure, the relationship between consultation and the nature of the type-certification processes is, in fact, challenging. But it is also reasonable to conclude that the EASA may be able to 'do better' than this. EASA could, in particular, follow the example of the Federal Aviation Administration and consult on *all* special conditions. That would prevent the current situation where the more open and contestable procedures are often escaped. Provision could also be made for the Panel of Experts' intervention to be sought in contexts where consulted parties have particularly serious concerns about how a certain dossier is being handled by the Agency.

⁸⁰³ *Ibidem*, see in particular: Comment Response Document for Airbus A380, SC D-43

Chapter VI

Conclusion

1- The new 'Euro-markets' and the institutional politics of distrust

The focus and the structure of the administrative state of the EU have evolved considerably during the last two decades. The Union has become much more closely connected with the regulation of highly specialised products and dynamic markets. That has implied both substantive and institutional shifts. Europe is doing new types of things, and is doing them through different bodies, actors and tools. From the late 1990s, that transformation was particularly visible in the scientific assessment of 'risks' and to a large extent reflected the wider impacts of the BSE crisis. There were fears about the Union's independence, credibility and capacity as a regulator and manager of complex risks. It was hence felt necessary to 'update' the institutional settings and ensure that the decisions that were being taken on the products benefited from the best possible technical advice. More recently, the concerns of the new administrative state seem to have turned towards a new type of market. Here, the lessons of the subprime crisis of 2008 are perhaps more important to understand the reasons for having more agencies and their interest in sectors which are highly networked. The issues with these markets is not just that products have to be "safe" and therefore considered by experts; it is also that the level of economic and financial interdependency has become so strong that more intense links between the Member States and their administrations have to be organised. Be it the third, fourth or fifth generation of (EU) agencies, the relevant point is that the markets which concern these bodies are of a much more dynamic and fluid nature. In such a context, it is hardly surprising that the EU has now created over thirty regulatory agencies, that their number keeps growing, and that the powers of these bodies are also becoming more significant.

The new administrative state has also grown alongside European comitology, not replaced it. The EU not only has more agencies than it had twenty years ago, it also has many more committees. The notion that the agencies supplement the 'old' administrative state might suggest two things. The first is that the agencies in fact do something that is substantially different from the EU committees' work; they engage with new problems and organise particular forms of social and technocratic interaction. The new administrative state (one might say) has consequently become important in its own right. On the other hand, it is also tempting to see the EU agencies as a further layer of a supranational bureaucracy on the rise. Agencies imply more, not less, EU government. While the first (internal) perspective suggests that the agencies are unique and that the controls on them might have to be different, the second point stresses that the more general challenge is to understand how administrative law should approach underworld technical structures which are bound to have their own dynamics and generate new problems.

The emergence of the new administrative state is also linked to problems of institutional trust, both within the Union's institutional framework and between the Member States' administrations. This politics of distrust (we shall say) increases the appetite for EU regulatory agencies. With respect to the Union's own issues of inter-institutional trust, at least since the Santer scandals and the food scares of the 1990s (mentioned above) there has been a clear discomfort in the European Parliament and the Council with respect to extending the regulatory competences of the Commission. Whereas the Commission had once been seen as an essentially capable, impartial and technically competent administrator, the perception today is different and it stresses a view of this institution as a self-interested bureaucracy which has become more politicized and prone to capture.⁸⁰⁴ The lack of confidence in the Commission, which is critical to understanding the role of modern EU agencies, is contemporary to problems of trust between national administrations. Mutual recognition between national regulatory processes has not worked, and that also explains why EU regulatory agencies have become necessary.⁸⁰⁵ One of the flaws in current reflections on EU agencies is the underplaying of these national conflicts. We are told that the supranational technocratic structures allow Europe to lay aside social and institutional tensions which had previously blocked the political integration process.⁸⁰⁶ The EU regulatory expert is portrayed, here, as committed solely to his own technical know-how and ethics. This position (which protects the Commission and exacerbates the differences between the EU political and technocratic worlds) overlooks that the 'former' conflicts might not go away by engaging in institutional engineering. It has also deviated attention from the pluralism of the institutional concerns within the EU agencies.

2- Problems for European regulatory capacity

The complex nature of the (new) euro-markets has placed strong demands on the capacity of the EU regulatory agencies to address the new challenges. We have seen that there are two inter-related types of issues with regard to this theme of European regulatory capacity: the *resources* (human, financial and institutional) which are needed to perform the technical work, and the nature of the relationship with more dynamic and fluid areas. Whereas 'resources' essentially refers to the manpower and to the physical means which are necessary to carry out the regulatory activities, 'dynamic markets' emphasise that the problems here are more unpredictable, vary from one sector to the next and that the public administration will then reflect this 'liquidity'. European regulatory agencies have limited internal resources. Their secretariats are small and the agencies structure more or less decentralised forms of interaction between the national competent authorities. This makes the agencies more dependent on the Member States for resources and makes them more vulnerable to external 'capture' by third parties.

⁸⁰⁴ G. Majone, *The Credibility Crisis of Community Regulation*, *Journal of Common Market Studies*, Vol. 38, No 2, 2000, p. 285-288

⁸⁰⁵ *Ibidem*, p. 280-281

⁸⁰⁶ M. Shapiro, *The Problems of Independent Agencies in the United States and the European Union*, *Journal of European Public Policy*, Vol. 4, No 2, 1997, p. 281-282

The internal capacity constraints of EU regulatory agencies implies that much of the work has to be outsourced (through contracts) to the national authorities. It is interesting that this is so, for the general perception is that the agencies were created precisely to allow the Commission to outsource technical tasks which could be better organised by specialised bodies. These 'power cascades' would suggest that it is becoming ever more difficult to control the exercise of this power. One of the paradoxes about the EU regulatory systems is that they may increase national regulatory responsibilities. Whereas one would expect that national regulatory capacities would be put under less pressure after an EU structure had been created, often the opposite happens and problems of national regulatory capacity can emerge. The power seems to be being 'pushed away' from the EU regulatory agencies (by the agencies themselves), in many different directions and with varying levels of intensity and that then creates a challenge in terms of how we can get hold of it.

If the EU agencies lack resources, the issue is not only whether and how institutionalised national interests can benefit; it is also that internal capacity constraints *increase* the reliance on the dynamics of the sector. There is an issue there about the possibly excessive level of proximity with the dominant forces of the market and how that can negatively affect 'smaller', underrepresented interests. The nature and intensity of such problems may vary (to be sure) depending on the type of task which is being pursued, the structure of the industry or the particular market context. At the same time, the fluidity of the new euro-markets would stress that the quality of the internal deliberation can be problematic, that it may be difficult to ensure 'checks and balances' within the process and that balanced communication between the experts (and the experts and the markets) can be complicated. Last but not least, there is a danger that the capacity constraints of EU agencies can put the effectiveness of the regulatory policies at risk. Those (institutional) limitations beg questions about the current powers and tools of EU regulatory agencies and whether they allow them to properly fulfil their technical mission and 'to deliver'.

3- Principles of fluid administrative law

In view of the dynamic, capacity-related dysfunctions, additional external and static formal constraints on the new administrative state will hardly help to improve things. Such proposals do not connect to the fluidity of the new administrative power and the problems it creates. Alternatively, having a set of constant administrative law principles to coordinate the operation of the agencies could be envisioned. These principles would seek to ensure that the dynamism and unpredictability of the new administrative state still holds a place for law in subjecting that fluidity to certain norms and values.

Fluid administrative law can hence be better understood as a set of values and an institutional framework that gives 'life' to those values. It stands in opposition to a static vision of administrative law. 'Static administrative law' may therefore be read as a conception of the organisation and control of the public administration which articulates three basic points: the direct association between formal administrative procedures and the dynamics emerging from the latter; the assumption that

administrative law problems can be understood *a priori* and that we have the instruments necessary to anticipate the type of risks which will be involved in particular institutional arrangements; and the underplaying of the process of European (administrative) integration as a phenomenon generating new institutional concerns related to the workings of the public administration. It is the resonance of static administrative law which, to an important extent, helps explain the current insistence on more judicial, political or parliamentary controls on EU agencies.

Principles of fluid administrative law therefore seek to identify and inject dynamic controls in the new administrative state. In EU comitology such controls exist. Fears about institutional drift and democratic accountability in those settings have also been followed by a better understanding of the new forms of 'checks and balances' emerging from the operation of those systems.⁸⁰⁷ With respect to the agencies, however, the dynamic checks on them are more undeveloped. Agencies require a greater emphasis on regulatory capacity, which also creates new problems. They are less based on open political argument, more reliant on expertise and technical resources, and organise links with the sector which have acquired significantly higher levels of intensity. The subsequent paragraphs therefore distinguish between (and develop) four fluid principles: internal process, external justification, commitment to pluralism and policy effectiveness. These principles will put pressure on the dynamics of the new administrative state and contain the existing institutional risks. The important point about the fluid law principles (whether we are talking about these particular four principles, or envisioning new ones) is that they have to go beyond the static imposition of certain administrative law 'goods' (e.g. transparency or participation). That, in itself, does not recognise the fluid nature of the new administrative state nor does it say why that dynamism should be regulated.

(i) Internal process

The internal process principle reflects a concern that institutions follow their own rules of procedure. Regulatory agencies, like other EU bodies, have to abide by certain internal procedures when they act and decide things. Those rules are either defined by the Regulation establishing the agency or through the latter's processes (via its management structures, for example). Internal procedures include norms on how decisions are adopted and the requirements of the agencies in that context. There are a number of reasons why we would want agencies to stick to their internal procedures. First, these ensure that a number of 'checks and balances' within the decision-making process are maintained. They also provide safeguards for third parties as to how institutional decisions are taken.⁸⁰⁸ Internal process provides, in addition, more material for external controls on the public administration. It seeks to ensure that the commitment to a particular institutional order may illuminate external actors about what the concerns and the alternatives are. Finally, the internal process principle stabilises expectations; it creates a belief outside the institution that matters will be handled in a certain way.

⁸⁰⁷ C. Joerges, *Deliberative Supranationalism: A Defence*, European Integration Online Papers, Vol. 5, No. 8, 2001, pp. 1-17

⁸⁰⁸ H. P. Nehl, *Principles of Administrative Procedure in EC Law*, Hart Publishing, 1999, p. 22

The fluid administrative state raises a question about how, and whether, internal rules of procedure effectively constrain the operation of the agencies. There is a risk that the dynamics of the agencies might escape some of these restrictions and create new problems. According to the case-law of the Courts, internal rules of procedure set out a particular way in which the relevant institution is to behave and respect for those procedures is important.⁸⁰⁹ Meanwhile, it is accepted that rules of internal process are not sacrosanct. The General Court has noted that wider concerns, namely of capacity, might have to be taken into account when considering whether an institution has disrespected own rules of procedure.⁸¹⁰ Even if, for example, the internal rules of an agency state that an external expert has to be consulted when certain “important” decisions are taken, that agency might not be able to ensure that it will always find someone who will be willing or able to comment on the matter. However, the principle also produces a set of duties of justification on the institution.⁸¹¹ Accordingly, (in a similar case) the same agency could still be asked to show that it has made a serious effort to find an external expert which might be interested in, and capable of, commenting on the issue under consideration. In this way (we shall see) the principle of internal process connects to the ‘next’ one (i.e. external justification). Fluid administrative law therefore suggests that non-compliance with internal procedures may be particularly problematic if it collides with any of the other three fluid principles (considered below): external justification, commitment to pluralism and policy effectiveness. That is not to say, however, that the internal process principle can be subsumed in those other values. The advantage of this principle is precisely that it emphasises the importance of the internal process and (as such) it generates its own duties for the concerned institution.

(ii) External justification

The principle of external justification places a duty on the new administrative state to give reasons for its decisions. The duty to give reasons for EU “legal acts” is regulated by Article 296(2) TFEU,⁸¹² and is also mentioned in Article 41(2) of the Charter of Fundamental Rights of the EU (in more general and open terms, under the ‘right to good administration’).⁸¹³ External justification imposes requirements on the new administrative state to explain why it has done things in a certain way, to be questioned by those affected by its power and to be responsible for the reasons which it offers. This allows external actors or patrols to understand the institution and its motives in a given case and it

⁸⁰⁹ See: Case T-185/05 *Italy v Commission*, ECR 2008 Page II-03207, on paragraph 43 and 44; Case T-113/05 *Angelidis v Parliament* [2007] OJ C 22, 26.1.2008, p. 42–42

⁸¹⁰ Case T-185/05 *Italy v Commission*, ECR 2008 Page II-03207, paragraph 127 and 149

⁸¹¹ *Ibidem*, paragraph 90

⁸¹² 296(2) TFEU: “Legal acts shall state the reasons on which they are based and shall refer to any proposals, initiatives, recommendations, requests or opinions required by the Treaties.”

⁸¹³ Article 41(2) of the Charter: “This [right to good administration] includes [...] the obligation of the administration to give reasons for its decisions.”

enables litigation.⁸¹⁴ But external justification also establishes a dynamic relationship between the new administrative state and those to whom reasons have been given. As such, the duty to give reasons is an important part of Bovens' understanding of accountability, which he sees as "a relationship between an actor and a forum in which the actor has an obligation to explain and justify his or her conduct, the forum can pose questions and pass judgement and the actor may face consequences."⁸¹⁵ External justification will therefore be important if it becomes an instrument of dialogue between the new administrative state and those affected by its power, "a commitment to do more than merely talk".⁸¹⁶

The EU legal system, however, does very little to require such an effort from the authorities. The case-law of the Courts holds a very narrow understanding of the duty to give reasons under EU law.⁸¹⁷ Reasons are only seen as a way to understand the administrative decision, which is a way to play down the importance of an exchange of views and responsiveness between the new administrative state and those with which it interacts.⁸¹⁸ There is also an issue about the link between the nature of external justification and the effects that public measures have on third parties. It is unclear, for example, whether the duty to give reasons (currently) provides a third party with the right to be heard in a given case before a decision on the matter which concerns him or her is adopted.⁸¹⁹ This is only required, it appears, where "restrictive measures are taken against the actors in question."⁸²⁰ The new administrative state will therefore be let off in a vast range of cases where its measures have a significant and negative impact on third parties without necessarily referring to that particular actor. Fluid administrative law proposes a more dynamic way of ascertaining where (and how) the duty to give reasons should be protected, and to what extent it should be so. Attention should be given to external justification not merely as a communication or dialogue-enhancing device, but equally as a principle which requires the administrative authorities to make a *strong case* in favour of whatever solution they consider appropriate. While it is clear that expecting the Courts to adjudicate on all sorts of conflicts between new administrative state and the concerned actors would carry the danger of shifting power to the judiciary without solving the important problem,⁸²¹ external justification (fluid) might also offer new institutional opportunities to structure and promote more responsive forms of EU public administration (see below). It is very important that the duty to give reasons may find a solid place in the context of a complex administrative state which is also concerned with other fluid principles and values.

⁸¹⁴ See: P. Craig, *EU administrative Law*, Oxford University Press, 2006, p. 382. See also: A. Türk, *Judicial Review in EU law*, Edward Elgar Pub, 2009, p. 114-115

⁸¹⁵ M. Bovens, *Analysing and Assessing Accountability: A Conceptual Framework*, European Law Journal, Vol. 13, No. 4, 2007, p. 450

⁸¹⁶ See: D. Chalmers et al, *European Union Law*, 2nd Edition, Cambridge University Press, 2010, p. 375. See also: H. P. Nehl, *Principles of Administrative Procedure in EC Law*, Oxford: Hart Publishing, 1999, p. 121-126

⁸¹⁷ Case C-113/00 *Spain v Commission*, ECR 2002 I-07601

⁸¹⁸ Supra 816, [Chalmers et al, 2010], p. 377

⁸¹⁹ *Ibidem*, p. 407

⁸²⁰ *Ibidem*

⁸²¹ M. Shapiro, *Who Guards the Guardians?: Judicial Control of Administration*, University of Georgia Press, 1988

(iii) Commitment to pluralism

The principle of ‘commitment to pluralism’ (or duty to take on board diffuse interests) considers who the new administrative state interacts with, whose views are being considered by its structures and to what extent so. It comes with the idea that it is not good if only certain groups or interests are included in the process while the concerns of others, neglected. An effort to accommodate diffuse interests also makes institutions (more) internally reflexive. They have to reconsider entrenched ideas and assumptions; think about new ways of addressing the relevant issues. Commitment to pluralism underlines a risk that well-organised interests might end up exerting undue influence over the new administrative state, that the latter’s policies might become confused with those of particular constituencies, losing sight of the general public interest. The new administrative state also creates new problems of institutional pluralism. EU agencies include twenty-seven different national competent authorities (each of which represents certain groups or has own views about the problems). There is a concern about the pluralism of those interactions as well.

EU law has not always had an easy relationship with this principle. In European standardisation processes, for example, there have been significant concerns about the “domination [of those] procedures by industry and the lack of constitutional guarantees”.⁸²² Here, consumer interests are represented before CEN (the largest European standardisation body) through ANEC (European Association for the Coordination of Consumer Representation), which sits (but does not vote) on the Technical Board of CEN.⁸²³ While ANEC tends to take advantage of these opportunities and submit opinions;⁸²⁴ it is unclear that this is enough to ensure a strong commitment to pluralism.⁸²⁵ Similar issues might confront stakeholder groups within EU agencies. Those fora will normally be sensitive to the interests of consumers, small and medium enterprises, users of the products, etc. The existence of those structures, the increasing provision for consultation with them and even their growing activism (see below) might not be sufficient, however, to ensure that the institutional systems in fact take on board a wider range of interests. If that is so, a ‘better’ effort towards pluralism may have to be required from the authorities. The important challenge may lie in the institutional capacity to ascertain where, how and to what extent pluralistic values ought to be promoted in the operation of particular systems and how the mechanics of that relationship might have to work in order to be productive.⁸²⁶

⁸²² D. Chalmers et al., *European Union Law*, 1st edition, Cambridge University Press, 2006, p. 495-496. See also: H. Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets*, Hart Publishing, 2005, p. 245-246

⁸²³ *Supra* 822, [Chalmers et al, 2006], p. 496

⁸²⁴ *Ibidem*

⁸²⁵ *Ibidem*. See also: H. Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets*, Hart Publishing, 2005, p. 245-246

⁸²⁶ See: R. Stewart, *The Transformation of American Administrative Law*, Harvard Law Review, Vol. 88, No. 8, 1975, pp. 1667-1813

(iv) Securing policy effectiveness

EU regulatory agencies are created to pursue certain policy goals (the EU medicines agency seeks to protect the health of patients and contribute to innovation in the pharmaceutical industry; the chemicals regulator should be able to evaluate and act upon the risks of chemical substances; the European aviation agency has to make sure that the new plane models meet safety requirements, etc). 'Securing policy effectiveness' emphasises that it is important that the agencies have the institutional ability to carry out the mission which they were created to perform and notes that internal capacity constraints can be an obstacle in that context. This fluid principle further suggests that the challenge here is not simply to constrain the power of EU regulatory agencies; it is also to enable them to (if required) acquire the powers or be granted the tools which are necessary to fulfil EU regulatory programmes and initiatives.⁸²⁷ 'Policy effectiveness' can be called into question (with particular intensity at least) if the existing problem of capacity is not confined to the agency itself but also extends to the EU regulatory system, which surrounds it. In cases where it is not possible (or desirable) to outsource tasks to the national authorities and an EU regulatory agency lacks resources, there is a danger that these bodies might underperform. In cases where one may observe serious obstacles to the accomplishment of the central regulatory objectives of the agency, 'securing policy effectiveness' would then stress that the structure, powers and *modus operandi* of that body should be reassessed. Moreover, 'securing policy effectiveness' can equally be put at risk if the policy itself is wrong (regardless of existing capacity constraints). This fluid principle therefore raises issues about reform of the agencies' regulatory procedures. With regard to capacity constraints, it suggests that there may be room for institutional creativity and it can be possible to do more with a similar level of internal resources. Moreover, 'securing policy effectiveness' is equally concerned with the institutional effects of the regulatory underperformance. It draws attention to the fact that in situations where the internal capacity constraints are very strong (and the work cannot be 'shipped out'), new dynamic dysfunctions may emerge if the agencies then start to engage in some kind of legal or policy entrepreneurship to get around the existing problems. Consequently, while 'policy effectiveness' accepts that feeble regulatory systems should not remain stuck in their own weaknesses, there are still questions about the way in which this is done.

4- Case-studies: dynamic institutional problems and controls

Having examined the four principles of fluid administrative law, the next step is to consider how these should be applied in each of the case-studies (agencies) and what kind of institutional 'solutions' could then be supported if we follow this approach. The thing about EU regulatory agencies, we have seen, is that they generate different types of problems. There is not a single set of institutional

⁸²⁷ On the idea that the purpose of a liberal constitutional order does not only seek to restrict public interference in private affairs but also to promote a set of own values, see: S. Macedo, *Transformative Constitutionalism and the Case of Religion: Defending the Moderate Hegemony of Liberalism*, in Constitutional Politics: Essays on Constitution Making, Maintenance, and Change, S. Barber and R. George (eds.), Princeton University Press, 2001

dysfunctions to be 'attacked', but rather a plurality of dynamics and of institutional risks. Some of these issues may be particularly pressing from the viewpoint of policy effectiveness. Others raise questions about the integrity of the internal process. Another possibility is that the difficulty lies essentially with external justification or with the level of commitment to pluralism. As such, the 'solution' to each agency's problem should have to be designed in accordance with its particular features and challenges. The link between the different proposals is provided by the existence of constant administrative law principles, as considered above. The fluid principles ensure that the different directions in which the dynamic controls may have to go are nevertheless united by a common set of ideas and values.

Moreover, the problems which the agencies create are unpredictable. They are only revealed through experience. That raises two sets of problems. First, it is doubtful that administrative law will be able to predict the risks that each agency will create (or at least there is a high degree of speculation in that exercise). Secondly, the fluid administrative state raises questions about the most appropriate way of structuring the fluid controls, institutionally. Fluid administrative law can be highly advantageous in this context since it has the openness to different sets of institutional concerns while it is sensitive to the mechanics of dynamic controls' design. It provides both a core set of administrative law values that have to be protected in the new administrative state and the institutional instruments to regulate their implementation (see below). Finally, fluid law is not only about imposing certain principles, in isolation, on the workings of the new administrative state. It also requires a dynamic relationship between these principles and communication between the aims which they mean to advance. It provides a framework that can be used to understand the existing institutional risks, organise controls and reflect on the benefits and limits of different solutions.

(i) EMA: the lack of an internal process

The European Medicines Agency (EMA) faces an internal process problem. The power of the Rapporteur is too difficult to control and the checks and balances within the process become diluted. There is a lack of internal pluralism in this system and the procedures lack vitality. Ultimately, this dynamic raises the danger that the quality of expertise produced by the Agency becomes lower due to internal dysfunctions. A fluid law proposal has to take these risks into account and consider how (and to what extent) the internal process may be reinvigorated. It is suggested that, with regard to this agency, dynamic controls be performed via the European Ombudsman. The intervention of the Ombudsman is (under these institutional conditions) arguably the most appropriate way of recalibrating the deliberative process and strengthening the procedures. This would work in two ways. First, the own investigation of the Ombudsman puts more pressure on the Rapporteur. Where this happens, internal controls are not reinvented but the responsibility of the more influential player increases. In this way, internal process becomes connected with the principle external justification (duty to give reasons). Secondly, the Ombudsman acts as an outside pressure that gives new energy to the internal procedures (and particularly to the aims which they seek to protect). The Ombudsman

inquiry will ask the EMA to rethink its handling of the dossier and that allows the scientific committee to get a stronger hold of the process. It is therefore not about having new procedures with more controls which will not work, but instead providing the opportunity to restate the importance of institutional pluralism in this decision-making. As such, the role of the Ombudsman brings the fluid principle of internal process and of commitment to pluralism closer. Pluralism, here, reflects the concern that weaker institutional interests and actors may become active players and have a say in these decisions. The link between pluralism and internal process also puts pressure on the notion that the problems of the new administrative state will not be solved by creating ever more controls within the process. With respect to the EMA, we saw that the real control (in the centralised procedure) has been the Member State Co-Rapporteur (which also evaluates the product, independently from the Rapporteur). There is, therefore, a certain degree of 'internal process' in this deliberative model (when the two Rapporteurs talk to each other), but we should try to make sure that other actors are also invited to participate. Also, there is an issue about the negative impacts on policy that other types of proposals could involve. Increasing the time that the scientific committee has to review the assessment of the Rapporteur, for example, might allow for rebalancing within the process, for example, but that would also raise questions about the wider impacts of a slower decision-making system. The important point, to conclude, is that the fluid law recommends a 'solution' which not only seeks to reinforce the internal procedures which have lost vitality (that narrow focus is a recipe for a failed new control) but that also looks to the principles of external justification, commitment to pluralism and securing policy effectiveness for inspiration.

(ii) ECHA: insufficient resources

The European Chemicals Agency (ECHA) confronts a challenge of policy effectiveness which has important impacts on its internal process. The failures of the registration system and the incapacity to control this through own resources have generated a dysfunction in the way that procedures are used. In particular, the authorisation process, which was meant to assess whether particularly dangerous substances should remain on the market, has acquired a more expansive role and is strongly relied on for fact-finding purposes. There are also problems (and limits) as to the extent to which the system can support 'more authorisations'; and this is hardly a viable option to normally deal with uncertainty about the existing chemicals, their uses and risks. A solution to these difficulties therefore has to give priority to 'securing policy effectiveness' and to the protection of the internal process as a form of stabilising expectations and preventing institutional malfunctions.

The first important thing would be to integrate other external capacities in the system. The ECHA could, in particular, rely on environmental NGOs to serve as patrols and support the Agency in the review of the industry registration dossiers and the missing data. The environmental patrols do not displace the basic authority of the Agency in the performance of this work, but inject new capabilities and energy in the system. One way to organise this collaboration would be to grant access to the data to the environmental group (or groups) and allow them, at the end, to attach an opinion on the

relevant file and concerning the data that is possibly missing. This would involve a change to the internal process as it currently stands but seeks to protect the stability of the objectives which the procedures are meant to ensure (namely that industry provides the data and that the EU regulatory process checks this and acts upon the risks). Still, it is clear that policy effectiveness can only be promoted (and the internal process 'restored') if companies in fact supply more data on their substances. More internal resources, alone, might not solve the problem. It can consequently be proposed that the Commission be given the power to fine companies which have consistently and repeatedly failed to provide the data or shown lack of a credible effort to acquire that information and supply it to the Agency. The Commission would have to receive the files from the Agency (with the opinions of the NGOs attached) and take a decision on whether a particular company should be fined for failure to provide mandatory data. This model conforms well to 'policy effectiveness' by increasing the pressure on the industry to fulfil its obligations. If that happens, the internal process would also have been restored. Finally, this solution also connects to 'commitment to pluralism' and 'external justification'. With regard to the former, the reformed model would be better at taking on board the interests of actors which are concerned by this regulatory process but nevertheless have little institutional expression in its operation. The commitment to pluralism does not appear here through the perspective of a deliberative process that needs fixing. Instead, what is at stake is the openness of the new administrative state vis-à-vis practical contributions of diffuse interests that can benefit the public interest. Secondly, the reformed structures would equally be beneficial from the angle of external justification. The use of the authorisation procedure, it would be made clear, would only be used if (really) no other alternative could be found. That increases the bond of responsibility between the new administrative state and those affected by its power.

(iii) CESR/ESMA and EASA: use of external capacities

The financial services and aviation case-studies emphasise problems related to external justification and commitment to pluralism in the new administrative state. Both of these agencies rely, to an important extent, on external capacities (sector/industry), which raises issues about 'capture' and undue influences in the operation of these regulatory systems. It also questions their promise of a politics of inclusiveness. Certainly, the nature of the challenges in these two sectors is not exactly the same. Whereas in the aviation type-certification procedures the agency deals with a specific industrial programme (external checks on this are inevitably limited to a few market or institutional actors), in financial services the range of interests concerned by ESMA's technical standards will understandably be higher. The important point, however, is that in both cases there are questions about how the relationship with the market works, what the level of public justification is and how the diffuse interests are (and should be) integrated in the decision-making.

The issue with European Aviation Safety Agency is that it has to work in the context of the constraints of particular industrial programmes, which are extremely complex and mostly concern the applicant. There is a strong case, still, for having more extensive consultations within the EASA type-certification

procedures (i.e. obligatory consultation of all 'special conditions'). It is about opening up the process where possible and forcing the regulator to provide reasons for its decisions. To be fair, more consultation does not necessarily imply better external justification. The duty to give reasons would also call for a true dialogue whereby the EASA has to respond to the comments it receives (which the Agency already does when consultation takes place). This proposal is also meant to ensure that an idea of internal process is protected. The current process of the EASA allows for some consultation and requires that the Panel of Experts comment on the important type-certification decisions. In practice, however, the system tends to ignore these procedures and this 'solution' addresses that challenge by asking the EASA to consult always. The promotion of pluralism under these conditions is particularly challenging. Fluid administrative law suggests that the commitment to take on board diffuse interests ought to be read in the context of other fluid principles (e.g. securing policy effectiveness) without forgetting about its fundamental dynamic demands. Policy effectiveness would indicate, in particular, that there are issues about (the possible level of) inclusiveness in the context of highly complex industrial programmes which have to address very serious safety concerns. In conclusion, fluid administrative law finds space for the requirement of more extensive consultation and could demand, in addition, that (during consultation) parties may call on the Panel of Experts to review the EASA team's performance where it is considered that there has been a clear failure to address an important issue of safety in the context of a type-certification programme. That would also give 'policy effectiveness' a more positive (and not only restrictive) role in the definition of the dynamic administrative controls.

With respect to ESMA, there are signs that following the introduction of the Securities and Markets Stakeholder Group, consultation is becoming more important and consumer interests (i.e. FIN-USE) are now more active in that process.⁸²⁸ It is very doubtful, however, that by simply having more consultation, the process will become more responsive or inclusive. It is therefore proposed that the ESMA Stakeholder Group be 'given' a limited number of yellow and red 'cards' to use in the course of the consultations. A 'yellow card' would imply that ESMA takes 'the utmost account' of the opinion of the stakeholder group. A 'red card', on the other hand, means that ESMA cannot propose the technical standards and has to present a revised version to the Stakeholder Group which takes into account the concerns expressed during consultation. The ESMA can then propose the measures provided that the Stakeholder Group gives green light to them and withdraws the 'red card'. The new powers of the stakeholder group are hence about having a stronger policeman in the deliberative process. This proposal is highly advantageous with respect to external justification. It fosters an effective communication and dialogue between the new administrative state and those affected by its power. It also suggests that the duty to give reasons may (at least under particular circumstances and where the risks of capture are very high) have to imply that the agencies make a very strong case in favour of their positions. This model would also be more pluralistic and have to show more

⁸²⁸ See: FIN-USE (Forum of User Experts in the Area of Financial Services) – List of opinions, broken down per year: the increase in the number of FIN-USE opinions (namely to CESR and to the Commission) has been particularly significant from 2009. Online at: http://ec.europa.eu/internal_market/fin-use_forum/documents/index_en.htm

commitment towards the integration of diffuse interests. With respect to the policy effectiveness principle, there appears to be a paradox in the proposed solution. While it arguably favours the objective of a higher level of consumer protection, there is also a risk that these 'red cards' may threaten other policy objectives which are also important. To escape this risk, the system could allow the ESMA to go ahead with the envisioned draft measures if it can show that these are of fundamental importance and urgent.

5- Structuring dynamic controls over time: the benefits of a new agency to apply the fluid law principles

The fact that we need all these different solutions in each regulatory agency (as considered above) shows how fluid administrative law has to be in order to deal with the problems of the new administrative state. This heterogeneity of solutions then raises issues with respect to the design and application of the latter. Importantly, in accordance with their founding Regulations, EU agencies have to be reviewed after a certain period (usually three years but it may be more).⁸²⁹ The institutional shape of the review model also varies. Concerning the agencies examined in this thesis: the European Medicines Agency and the European Markets and Securities Authority are reviewed by the Commission, the review of the operation of the European Aviation Safety is carried out by consultancy groups, and the European Chemicals Agency performs its own review.⁸³⁰ In addition, regardless of the institution responsible for the review, the system is very open and unclear about what this evaluation is about and in accordance with which criteria are the agencies being assessed. Usually, the review of the agencies is used to consider the experience with the application of the relevant regulatory regime (e.g. REACH, in the chemicals sector), while in other sectors (e.g. aviation), the review procedure also looks at the internal practices of the agencies and their working procedures. The assessment of the internal practices of agencies is seen, here, from the perspective of efficiency and taking into account the overall objectives of the EU regulatory programmes. It holds a narrow minded focus on policy effectiveness and disregards other types of institutional concerns.

If we look back at the four principles of fluid administrative law considered above, this is an unsatisfactory situation. As the problems which EU agencies create are highly dynamic in nature, that is, only after there has been some degree of experience with their operation it is possible to understand the existing challenges and capacity constraints; the review process of the agencies would be a very good opportunity to address those (four) issues. It offers unique conditions to both understand the nature of the new administrative power and structure dynamic controls. In order to pursue that objective effectively, the institutional capacity of the EU review system is important. It is

⁸²⁹ Article 62: Regulation (EC) No 216/2008 of the European Parliament and of the Council (European Aviation Safety Agency), *OJ L 79*, 19.3.2008, p. 1–49; Article 86: Regulation (EC) No 726/2004 of the European Parliament and of the Council (European Medicines Agency), *OJ L 136*, 30.4.2004, p. 1–33; Article 117(2): Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH), *OJ L 396*, 30.12.2006, p. 1–849; Article 81: Regulation (EU) No 1095/2010 of the European and the Council (ESMA), *OJ L 331*, 15.12.2010, p. 84–119

⁸³⁰ *Ibidem*

therefore proposed that a new EU agency be created to fill that gap. This agency will be responsible for the review of EU regulatory agencies and would be asked to (in the context of those reviews) submit proposals for each agency in accordance with the (four) fluid administrative law principles. The new agency could integrate highly qualified public servants with expertise in administrative law, regulatory policy, economics as well as sector-specific experts for each EU agency. It should be able to take hearings, pursue own research and carry out reviews on its own initiative. The new 'super-agency' proposed here should not have to be a very expensive and big structure. It would be possible to generate the capacity to perform this type of mission without spending too much EU money and by also relying on contributions from national officials.

The new agency would ensure dedication to the study of fluid institutional risks. We have seen that there are, in fact, some dynamic controls in the new administrative state but this is undeveloped and the structure of these checks lacks overall vision and coherence from an administrative law perspective. There is currently a lack of legal instruments to assess and organise fluid controls in the new administrative state, and the result of that has also been the insistence on external and static checks on the EU agencies. In their analysis of 'real' EU accountability, Curtin, Bovens and Hart note that counterterrorism experts and crime fighters "are fond of saying that it takes a network to catch a network" only to then come to terms with the idea that "from an accountability perspective the simultaneous dispersal of both actors and forums into networks creates a whole new set of challenges."⁸³¹ Instead of a 'network to catch a network', fluid law stresses that we need a new institutional *system* to get hold of the dynamic administrative state.

The creation of a new agency to police the EU regulatory agencies raises a guardianship-type question: who will be guarding the new guardian?⁸³² It has been noted elsewhere that one of the problems about guardianship "is that we tend to deal with failures of trust by accumulating more and more layers of guardianship", and the creation of a new agency may be seen as reflecting a similar tension.⁸³³ However, having a 'new guardian' has clear advantages in this context. The control of the new agency could be addressed much more easily; it would hardly raise the plural and unpredictable type of problems that we see in the new administrative state. Still, the new agency should also have to comply with the fluid principles (considered above) and could perhaps report to the Commission on this, namely in the context of its own review process.

Finally, the proposal to create a new EU agency to police the regulatory agencies begs questions with regard to its institutional content and how it relates to European integration more generally. This thesis began by underlining an important difference between the nature, structure and purpose of

⁸³¹ M. Bovens, D. Curtin, P. Hart (eds.), *The Real world of EU Accountability: What Deficit?*, Oxford University Press, 2010, p. 192

⁸³² *Supra* 821, [Shapiro, *Who Guards the Guardians*, 1988]

⁸³³ I. Ayres and J. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, 1992, p. 57. See also: S. Shapiro, *The Social Control of Impersonal Trust*, *American Journal of Sociology*, Vol. 93, No. 3, 1987, pp. 623-658

national regulatory agencies and the 'EU version' of these bodies. In this way, it was attempted to underline a fundamental distinction between the dynamics of national regulatory or administrative processes and the particular rhythm, characteristics and problems which the new administrative state of the EU faces (and how that affects the problem of 'control'). There is still an issue, however, about whether (and why) the EU should be worried about this. Part of the answer may be in the notion that there is a strong link between the nature of the EU and the importance of institutional challenge and experimentation. One of the defining characteristics of the EU is that because its existence is 'questioned every day' there is a pressure to engage with new experiments and ideas which (it is thought) will secure higher levels of public acceptability and recognition. There is a sense of ongoing self-doubt in the Union which, while carrying its own problems, makes us always look for better institutional alternatives and reforms. Fluid administrative law is an example of this. It is not just that in national contexts the new administrative state is less fluid. It is also that because we have novel European institutional structures, there is an attempt to conceive new ways of dealing with problems that, in some way or another, are also not completely foreign to national democratic processes.

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Respondent 1d (Commission)

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Respondent 4d (European Parliament)

(iv) European Aviation Safety Agency

Respondent 1c (EASA)

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