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Luis Barroso

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THE CHALLENGES OF THE NEW ADMINISTRATIVE STATE OF THE EUROPEAN UNION AND THE CASE FOR A FLUID LAW OF CONTROLS

By Luis Barroso[*]

Introduction

Over the last fifteen to twenty years the shape of the European public administration has changed considerably. At least since the 'mad cow crisis', forms of EU social and economic intervention have become more tightly connected with the regulation of complex and risky 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 these markets shows that formal law-making is but one of the ways through which the Union exercises its authority and new forms of public intervention are becoming more important. The EU, 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 of the economy or the supervision of financial actors and institutions.

One of the effects of the new Euro-products 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 regulation makes it too difficult for matters to be handled by the Commission, or by national competent authorities acting alone. European regulatory agencies are not really, however, an EU 'equivalent' of their national partners. They have been given little resources of their own and organize decentralized forms of regulatory cooperation between national authorities and the regulated markets. While the powers of the regulatory agencies vary considerably, overall these bodies take on certain executive responsibilities in their own field of action,

[*] I would like to thank Kenneth Armstrong and Kalypso Nicolaïdis for valuable comments on a previous draft of this paper. All errors and omissions are mine.

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 growth of the EU agency phenomenon has led to fears that we may be lacking equally significant controls on its power. The Lisbon Treaty has now formally introduced the possibility of EU agency acts falling under the jurisdiction of the Courts if legal effects on third parties are produced. Proposals for increased parliamentary surveillance of EU regulatory agencies are also being heard. It is questionable, however, that the strengthening of a formal and external constraint will do away with problems that are mainly capacity-related and dynamic in nature. The imposition of strict reviews on the regulatory agencies underplays the liquid interactions within them and the problems of a poorly resourced administrative system. As EU regulatory agencies become relevant players in the implementation of EU law, however, there is a clear interest in a better understanding of the administrative underworld and in looking for adequate controls on its operations.

The paper is organized as follows: first, the implementation of EU law and the position of regulatory agencies shall be considered. Secondly, the transformation of the European administrative state will be examined. The third section considers the mechanics of formal accountability. Subsequently, the decentralized and dynamic nature of the new administrative state is looked at. In that context, the experience with the operation of two EU regulatory agencies (in the medicines and chemicals sectors) is observed. The fifth section then explores principles of fluid administrative law as an alternative response to the growth of EU regulatory agencies. The final section reflects on the implications of those principles for 'checks and balances'. It will be concluded that a more flexible substantiation of constant legal principles in the public administration on the basis of which new controls on agencies may emerge would be preferable to the current insistence on further and increasingly formal structures of accountability in this area.

I. The implementation of EU law and the regulatory agencies

Before the European Union decided to introduce regulatory agencies to perform a series of complex tasks, the executive power of the Union was concentrated on the Commission. The Commission has not traditionally had, however, wide-ranging powers

of direct administration as the primary responsibility for implementing European Law remains at the national level. As Piris explains, the EU 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".[1] In cases, though, where "centralisation has been judged necessary", the Commission was handed direct responsibility to implement EU policies (e.g. competition policy and implementation of the EU budget).[2] The Commission also has a number of other powers: legislative and quasi-legislative, agenda-setting and supervisory competences.[3] As a consequence of the concentration of many functions in the Commission much pressure was placed on its resources, which led to a preference for "delegating specialised and time-consuming tasks to independent agencies and offices rather than using the Commission as a repository for further regulatory competences."[4]

The reaction of the Courts to the emergence of EU agencies, which dates back to the time of the High Authority of the Coal and Steel Community, was to constrain the conditions under which a delegation of powers to new bodies (the existence of which had not been predicted by the Treaties) could legitimately take place. Those limits were explained in *Meroni* (1958).[5] The case concerned two private law organizations (known as the 'Brussels agencies') established in the context of an equalisation system to prevent the prices of ferrous scrap within the Community from being aligned on the higher prices of ferrous scrap that had been imported. The Court observed, first, that the Commission was delegating to new bodies powers which it did not possess. Secondly, there was concern with the lack of judicial controls on decisions taken by the Brussels agencies.[6] The Court then went on to note that the consequences of a delegation of regulatory powers are very different depending on whether it concerns clearly defined technical competences or not. If regulatory agencies were given a wide margin of discretion in their activities and the ability to make complex policy assessments, that

[1] J. C. Piris, *The Lisbon Treaty: A Legal and Political Analysis*, Cambridge University Press, 2010, p. 98
[2] *Ibidem*, p. 97-98
[3] D. Chalmers et al, *European Union Law*, 2nd Edition, Cambridge University Press, 2010, p. 59-64
[4] *Ibidem*, p. 66
[5] Case 10/56 *Meroni v High Authority*, ECR English special edition Page 00157
[6] *Ibidem*, p. 171

would be incompatible with the "balance of powers" which the Treaties seek to protect.[7] According to one academic view, the judgment asks too much to ask of EU law. As the Union (then Community) is politically and constitutionally "unsettled", the creation of institutional substructures at EU level is important to ensure space for productive coordination between national and social actors.[8] Instead of valuing the enabling role of EU law, *Meroni* (in this view) holds on to a rather rigid and static understanding of institutional balance and the rule of law.

Be it as it may, we shall see below that *Meroni* is relevant, still today, not just for what it prohibits, but for what it has allowed the EU to do in terms of delegating regulatory powers to agencies. Moreover, the legal constraints outlined above should be read in the context of recent (Lisbon) Treaty changes. Acts of EU agencies are now formally subject to judicial review, primarily through Article 263 TFEU (see below). The Lisbon Treaty has also clarified the way in which the control of Commission implementing powers is to work (through Articles 290 and 291 TFEU). Since the early days of the European project, the Court accepted that the Council could delegate "general implementing powers" to the Commission in order to pursue the basic objectives defined by the legislator.[9] The Council was also entitled to check the performance of the Commission at technical/implementing level through committees of national representatives (the system known as 'comitology'). The wide and general powers transferred to the Commission at the implementation stage were problematic for democratic accountability reasons and contrasted with the strict conditions which the Court had established in *Meroni* for the delegation of powers from the Commission to agencies. The Lisbon Treaty has now introduced a distinction between delegated acts (Article 290 TFEU) and implementing acts (Article 291 TFEU), and includes different instruments for the control of the Commission at each level. With respect to "delegated acts", these will be used whenever the Commission is given the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act. Here, the control of the Commission falls exclusively on

[7] *Ibidem*, p. 173
[8] Everson, M., *Administering Europe?*, Journal of Common Market Studies, Vol. 36, No. 2, 2002 , pp. 195-216
[9] C. F. Bergström, *Comitology: Delegation of Powers in the European Union and the Committee System*, Oxford University Press, 2005, p. 2

the Council and Parliament (as legislators). But the Commission may also be empowered to adopt "implementing acts" where uniform conditions for implementing EU laws are necessary. In that case, the controls on the Commission should be performed by the Member States (Article 291 TFEU), through modernized comitology procedures.[10]

With regard to EU agencies, it is not (yet) fully clear how Article 290 and particularly Article 291 TFEU may affect their formal position in the implementation of EU law. Agencies are not mentioned in either article. However, the relationship of EU agencies with each of those provisions may also be read differently. Following *Meroni*, it is settled that agencies cannot be given powers to adopt delegated acts (i.e. quasi-legislative competence). These acts are reserved to the Commission, so as to preserve democratic accountability and inter-institutional 'checks and balances'. The situation of EU agencies in Article 291 TFEU is more controversial, however. Implementing acts (Art. 291 TFEU) can involve both "regulatory acts" (i.e. implementing measures of general application, in the sense of Article 263(4)) and individual administrative decisions.[11] With regard to the latter, several EU regulatory agencies have already been given powers to adopt decisions binding on third parties, and the legality of this is made clear by the insertion of Article 263 TFEU, which allows for judicial control of such acts. The Treaty is less precise concerning the question of whether EU agencies may adopt regulatory acts of general application that only implement the legislative act, instead of interfering with its content within the meaning of Article 290 TFEU.[12] While a quick reading of Article 291 TFEU and *Meroni* might suggest the answer is 'no', Article 277 TFEU (plea of illegality) now provides for judicial review of acts of "general application" adopted, among others, by EU agencies (which seems to confuse things a little bit).[13] In the next section we shall see that the dynamic is one of growth and reinforcement of regulatory agency authority in the governance of complex European markets.

[10] Regulation (EU) No 182/2011 of the European Parliament and the Council, *OJ L55/13 28.2.201, p. 13-18*

[11] See: Opinion of Advocate General Jääskinen delivered on 12 September 2013, C-270/12, United Kingdom v. Council and Parliament, Application: *OJ C 273 from 08.09.2012, p.3*. See paragraphs 76-82

[12] *Ibidem*

[13] *Ibidem*

II. The transformation of the EU administrative state

In 1975 the first European agencies were introduced with the establishment of the European Centre for the Development of Vocational Training (Cedefop)[14] and the European Foundation for the Improvement of Living and Working conditions (EUROFUND).[15] These bodies were mainly created for information collection purposes. They were given very limited powers and the idea behind them was mainly that the Commission should outsource particularly time-consuming and specialised tasks, allowing it to focus on its core functions of policy initiation and implementation.[16] The reliance on regulatory agencies acquired new momentum during the 1990s, in the context of the completion of the internal market. During that decade eleven EU regulatory agencies were introduced.[17] Most of those bodies were created for the collection and analysis of information. One of the bodies which stand out, however, is the European Medicines Agency (EMA). The EMA is responsible for the scientific evaluation of medicines in the EU and its central responsibility is the assessment of particularly innovative medicines (namely those derived from biotechnological processes) through the so called 'centralised procedure'. This agency opened up a new layer of product approvals, which was mandatory for 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.

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

[14] Council Regulation (EEC) No. 337/75, *OL L39, 13.2.1975, p. 1–4*
[15] Council Regulation (EEC) No. 1365/75, *OJ L 139, 30.5.1975, p. 1–4*
[16] Supra 3, [Chalmers et al, 2010], p. 66
[17] The European Environmental Agency (EEA); the European Training Foundation (ETF), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA); the European Medicines Agency (EMA); the Office for Harmonisation of the Internal Market (OHIM); the European Agency for Health and Safety at work (EU-OSHA); the Community Plant Variety Office (CPVO); the European Institute for Gender Equality (EIGE); the Translation Centre for Bodies of the European Union (CdT); the European Monitoring Centre for Racism and Xenophobia (EUMC); and the European Agency for Reconstruction (EAR)

the Commission.[18] The independence and competence of the Commission (as a regulator) was 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 blow to the credibility of the Commission.[19] This period has 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 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.[20] 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.[21] The Commission considered the advantage of agencies to be "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."[22]

Following the BSE crisis, another eleven EU regulatory agencies were set up. While the functions of these agencies vary considerably, the "most wide-ranging power" granted to many of these bodies 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."[23] Whereas EU institutions are not obliged to follow these 'opinions', "there is invariably a duty to consult the agency" before departing from the latter's advice.[24] 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."[25] This then "allows both the acquisition of

[18] Supra 3, [Chalmers et al, 2010], p. 66
[19] 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
[20] European Commission – 'Reforming the Commission', COM(2000) 200, Part I, 6
[21] European Commission – 'European Governance: A White Paper', Brussels, 25.7.2001, COM(2001) 428 final
[22] *Ibidem*, p. 24
[23] Supra 3, [Chalmers et al, 2010], p. 66
[24] *Ibidem*
[25] *Ibidem;* see: Case T-13/99 *Pfizer animal Health vs. Council* [2002] ECR II – 3305, p. 380-2

new EU capacities and the taking of important decisions behind the cloak of 'expertise'".[26] 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".[27]

More recently, a new breed of EU regulatory systems has emerged, in the fields of financial services, energy and electronic telecommunications. The power of this 'forth wave' of EU regulatory agencies lies not so much on the weight of scientific advice but on their capacity to intensify the links between the national competent authorities in sectors where the spillover effects of uncoordinated market supervision is particularly problematic. Such concerns are visible, for example, in the mandate of the Agency for the Cooperation of Energy Regulators (ACER), which is empowered to take decisions on infrastructure affecting two or more Member States; or in the Body of European Regulators for Electronic Communications (BEREC), which is seeking to develop coordinated regulatory practices in Europe by fostering the consistency of national market remedies.[28] Also, the European Securities and Markets Authority (ESMA) has been given powers of direct intervention, through legally binding acts, in the financial markets of Member States where there is a "threat to the orderly functioning and integrity of financial markets or to the stability of the whole or part of the financial system in the Union".[29] This applies in 'short-selling and certain aspects of credit default swaps', and includes a power to impose on natural or legal persons: notification and disclosure obligations, a prohibition on the performance of certain market transactions or a requirement to do so under particular conditions.[30] The ESMA responsibilities are also peculiar in that they can be imposed in substitution of a decision or inaction by the concerned national competent authority. These are far-reaching powers and the legality

[26] *Ibidem*
[27] L. Azoulay, *The Court of Justice and the Administrative Governance*, European Law Journal, Vol. 7, No. 4, 2001, p. 428
[28] Regulation (EC) No. 713/2009 of the European Parliament and of the Council, *OJ L 211, 14.8.2009, p. 1–14.* See also: BEREC – 'Work Programme 2011' – BEREC Board of Regulators, December 2010, BoR (10) 43 Rev1
[29] Regulation (EU) 236/2012 of the European Parliament and the Council, *OJ L 86/1, 24.03.2012*, Article 28
[30] *Ibidem*

of this is being disputed.[31] Finally, the new agencies have been given tasks of a more operational nature, such as carrying out inspections. An example of this is ESMA's responsibility for the supervision of credit rating agencies in Europe, which includes, among other things, a power to fine the rating agencies if they fail to comply with EU legal obligations.[32] Taking into account the extraordinary importance of concerns with the supply of capital in Europe, the ESMA supervision of credit rating agencies is significant and shows that the EU has come a long way since a decision was made to set up a few data collection agencies to support the Commission in the 1970s.

III. The mechanics of formal accountability

The growth of the new administrative state of the EU has raised concerns that we may be lacking equally significant controls on its operation. Calls for increased political and judicial constraints on the agencies have therefore been heard.[33] As noted above, the Lisbon Treaty has formally introduced the possibility of judicial control of EU agency acts intended to produce legal effects on third parties (Article 263 TFEU). Proposals are also being made to increase forms of political and parliamentary oversight on the agencies.[34] 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 could be enhanced.[35]

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[31] Case C-270/12, United Kingdom v Council and Parliament, Application: *OJ C 273, 08.09.2012, p.3*. While the Court has not yet decided on this case, the opinion of the Advocate General (AG) suggests that the Regulation may be declared illegal, albeit for legal basis reasons. For the AG, the legislative authority granted to the Union under Article 114 TFEU (general legal basis to harmonise national laws in the field of internal market) is at odds with the wider institutional and centralizing ambitions of Article 28 of the contested Regulation. On the other hand, however, the AG rejects the argument that the powers given to ESMA are in violation of *Meroni*. The AG sees no strong objection in giving EU agencies the power to adopt general regulatory acts as long as they are non-legislative in character (within the meaning of Article 291 TFEU). In reaching that conclusion, the AG outlines the importance of new judicial controls on EU agencies, through the insertion of Articles 263 and 277 TFEU

[32] 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

[33] 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

[34] *Ibidem*

[35] *Ibidem*

(i) Judicial controls on EU regulatory agencies

A traditional concern with EU regulatory agencies is that judicial controls on their power may be weak. It is helpful to distinguish the review of EU agency 'opinions' from problems which emerge in the scrutiny of their 'legally binding' acts. As mentioned above, the power of EU regulatory agencies is often in the supply of technical expertise (opinions) to the Commission, which the latter then relies on for the adoption of regulatory decisions. In such cases, the Court has accepted that while the technical (agency) opinion itself is not a direct source of legal effects, its importance in decision-making can be such that it deserves to be judicially examined.[36] The Court is therefore able to check both the formal legality of an agency's opinion and the Commission's exercise of discretion.[37] The Court explains that formal legality review concerns the proper functioning of the agency technical committee which provided the Opinion, the internal consistency of that recommendation and the statement of reasons which has been provided.[38] The Court may not, however, substitute its own views for those of the agency.[39] A difficulty with formal reviews on the expertise may be the disregard for the material risks of decision-making, particularly in an administrative context that is decentralized and more liquid in its institutional interactions.

The typical situation where Article 263 TFEU would apply concerns decisions adopted by EU agencies which directly affect third parties. The new Treaty article implies that Courts now have to consider what that provision allows them to do, i.e. what type of acts are understood to generate *legal* effects on some external interest. 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 can or will review acts of EU agencies that directly imply consequences for third parties but which only 'prepare' subsequent regulatory measures (e.g. in the context of an EU authorisation procedure). Judicial intrusions in the inner world of the administrative state may have to be limited to prevent litigation from being systematically used by powerful social and economic interests against all sorts of regulatory decisions that somehow affect them in a negative

[36] 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
[37] *Ibidem*, parag 199
[38] *Ibidem*, parag 200
[39] *Ibidem*

way. However, the complexity of modern product regulation can also imply that important decisions are taken by an agency before it finally decides on the relevant matter. The subjection of a certain product to an EU authorization procedure can, for example, lead to a generalized fear in the market that it will be banned and shift the preference of distributors or consumers towards other products available on the market. In such cases there is a question about the scope of judicial review and whether a formal legal check is the best way to ensure the control of preparatory and fluid regulatory decisions.

(ii) Parliamentary scrutiny and EU regulatory agencies

The rising profile of EU regulatory agencies has also led many to believe that it would be advisable to strengthen political controls on their operation, namely through tighter parliamentary supervision.[40] The European Parliament's scrutiny of regulatory agencies touches on both the performance of the technical work and on budgetary/financial related matters.[41] Regarding the regulatory activities as such, the Parliament examines 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".[42] 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."[43] The EP also has responsibilities in the review of the budgetary and financial life of regulatory agencies. Through the discharge procedure, the Parliament is asked to politically approve the implementation of the agencies' budgets.[44] If the Parliament believes there is a problem, it may postpone or refuse the discharge.[45] This happened for the first time in May of 2011, when the Parliament decided to postpone the 2009 budget discharge for

[40] 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
[41] M. Busuioc, *The Accountability of European Agencies, Legal Provisions and Ongoing Practices*, Eburon, 2010, p. 98
[42] *Ibidem*, p. 130
[43] *Ibidem*. p. 131
[44] *Ibidem*, p. 152
[45] *Ibidem*, p. 155

the European Medicines Agency and the European Police College (CEPOL).[46] Whereas the case of CEPOL concerns non-compliance with the EU Financial Regulation, the problems with the medicines agency involved an alleged lack of independence of its experts, questions over its hiring practices and charges of conflicts of interest between agency officials and the pharmaceutical industry.[47]

Overall, the push for greater parliamentary controls on EU regulatory agencies should not overlook the lack of resources and expertise of the EP to carry out that mission well. The Parliament's difficult experience in the control of Commission implementing powers (comitology) deserves to be remembered here. While the Parliament fought, for a long time, in order to be granted equal footing with the Council in the supervision of EU comitology, once it got those powers it failed to give them effect. It was the Council, more than the Parliament, which benefited most from the introduction of the 'regulatory procedure with scrutiny', in 2006.[48] The lack of inter-institutional controls in EU comitology has not meant, however, that the exercise of Commission implementing powers comes unchecked.[49] Looking into the dynamics of comitology in the food sector, Joerges and Neyer observed that the system did not so much involve national political controls on the Commission but rather worked along more fluid and problem-solving lines, generating a "Europeanized inter-administrative discourse characterised by mutual learning and an understanding of each other's difficulties in the implementation of specific solutions."[50] Considering the higher levels of complexity and sophistication which go into EU regulatory agency activity, the suspicion that European political institutions have limited capacity to police the operation of these systems is only stronger. A question, then, concerns the quality of the institutional interactions within the agencies and the understanding of whether (and how) built-in controls on the expertise may ease some of the concerns with the de-

[46] 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
[47] *Ibidem*
[48] Supra 3, [Chalmers et al, 2010], p. 120-121
[49] 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
[50] *Ibidem*

politicization of the new administrative state. We will see now that the resources constraints of EU regulatory agencies are challenging in this regard and generate new administrative problems.

IV. The decentralized and dynamic EU administrative state

The creation of EU regulatory agencies affects the relationship between national competent authorities and expert communities in important ways. Majone has noted that EU agencies were a solution to ongoing conflicts between national regulatory offices in a number of sectors.[51] The dependence on mutual recognition (for the authorisation of medicines, for example) was not working as the assessments of national competent authorities diverged too frequently. One of the paradoxes about the creation of European regulatory agencies, however, is that while an effort has been made to centralize decision-making and overcome the deficits of mutual recognition, the structure and operation of the agencies is highly decentralized. EU regulatory agencies have been given very limited own resources and rely extensively on the capacities of Member States. The secretariats of EU regulatory agencies are small and deal mostly with administrative issues, while most of the technical/scientific work is performed by national authorities through systems of networking and inter-national collaboration between experts. An advantage of a 're-decentralization' through the creation of EU regulatory networks is that it puts less pressure on the financial and human resources of the Union while allowing the latter to benefit from existing national expertise. However, if EU agencies have to rely too much on the resources of national bodies there is arguably a greater possibility of 'capture' by partial interests. Moreover, there is a danger that EU agencies become particularly reliant on the resources provided by a few national competent authorities, while others assume an irrelevant position. Finally, internal controls on the expertise may be weakened in a decentralized and imbalanced system. If the technical work gets transferred to all kinds of different places, it may be harder to control what is really going on and to introduce adequate 'checks and balances' and reviews on the experts' work. The more general risk is that the quality of the expertise produced by EU agencies turns out of be of lower quality.

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

A further challenge for EU agencies concerns the interaction with products and market activities that are highly fluid and dynamic. Regulatory agencies allow the Union to acquire institutional capacities to address new transnational challenges in social and economic areas of complexity.[52] Many of those problems do not concern European 'versus' national tensions. Their material dimension is important: "they are government practices concerned with doing things, structured, above all, by the contingency and parameters of the events with which they deal."[53] Moreover, EU administrative developments are not just "novel spatially in that they re-territorialize law and politics"; they are also "novel materially in that they react to new challenges".[54] While some of these "are inspired by technology (e.g. biotechnology, internet regulation, future markets in financial services)" others "are inspired by the need to create new public goods (...)".[55] A consequence for the agencies is that the particular things which they do, and the institutional constraints under which they operate, shape the quality and difficulties of each regulatory regime. In this regard, the fact that the agencies deal with a particular kind of new 'European product' is important and may come with significant institutional consequences (see below). The subsequent paragraphs look at the operation of two EU regulatory agencies, in the fields of medicines and chemical regulation, so as to further explore the dynamic challenges of the new administrative state.

(i) Outsourcing and institutional imbalances

As EU regulatory agencies have little resources of their own, it is often the case that the scientific/technical work is outsourced to the national competent authorities, which may then have to report back to the agency and share the results with other national authorities. This begs a question as to how much work is outsourced and whether this was intended in the first place. Secondly, it is unclear how a decentralized system promotes internal controls on the expertise and deliberation. There is a risk that if EU

[52] 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
[53] D. Chalmers, *Deliberative Supranationalism and the Reterritorialisation of Authority*, EUI Working Paper 2005/12, pg. 34
[54] *Ibidem*, p. 34 and 35
[55] *Ibidem*

agencies do not have the capacity to perform the relevant scientific tasks in-house, the national authorities will have to police each other's share of responsibilities, which may be a difficult thing to do. An example of an EU agency where the partnership with national competent authorities is salient is the European Medicines Agency (EMA). This body was established in 1995 to provide an institutional support to the centralized procedure for the authorization of medicines, which was created in that same moment. The centralized procedure allows companies to apply for an authorization of their products through this EU agency and if they are successful, the medicines can then be marketed all over the European Union territory.[56] While it is the Commission that formally authorizes the medicinal products, the EMA provides scientific advice and it is common practice that the Commission follows the technical opinions. The centralized procedure does not work for all types of medicines, however. It was initially reserved to products derived from biotechnology, and while its scope was expanded over the years, it continues to be mostly used for new medicines which involve higher levels of innovation (the so called 'new active substances').[57] Other, more traditional and local medicines are usually assessed either through purely national or via reformed mutual recognition procedures.

When the EMA receives an application for a marketing authorization, it hands the responsibility for the scientific evaluation of that product to one of the national competent authorities (the Rapporteur). There may also be a Co-Rapporteur to perform a second, independent evaluation of the product. The Rapporteurs then have to report back to the Committee for Human Medicinal Products (CHMP) of the Agency, where the other national competent authorities may raise objections to the Rapporteurs' evaluations. In practice, however, these internal controls do not work well. It has been observed that as soon as the two national Rapporteurs agree on their evaluations, the role of the CHMP becomes irrelevant.[58] Only when the Rapporteurs disagree is the CHMP able to intervene so as to determine who is right and only that. The characteristics of the 'centralized procedure' medicines, which are innovative and

[56] 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*

[57] L. Barroso, *The Problems and the Controls of the New Administrative State of the European Union,* PhD thesis, London School of Economics and Political Science (LSE), 2011. See p. 47-51

[58] *Ibidem,* p. 60-62

complex products, are important to understand the prevalence of the Rapporteur in decision-making. Unlike more traditional medicines, new active substances have no previous market history. It becomes harder for national authorities which did not participate in the initial assessment of the products to come up with well-founded objections. The consequence is a system which lacks internal controls on the expertise. Moreover, only five Member States are given the role of Rapporteurs in this system (i.e. Germany, France, Sweden, the Netherlands and Denmark), with few exceptions.[59]

(ii) Insufficient resources and policy failure

The lack of resources of EU agencies and their dependence on external actors may also imply risks for the effectiveness of the policy being pursued. One agency which appears to be struggling as a consequence of complex regulation and limited internal capacities is the European Chemicals Agency (ECHA).[60] This agency was established in 2006 to administer the new EU regulatory program for the chemicals sector: REACH (registration, evaluation and authorization of chemicals).[61] Whereas the previous regulatory regime made a distinction between 'new' and 'existing' chemical substances and had different rules for each, REACH establishes a single system for all chemicals. The previous model had failed to deal with the risks posed by older chemicals in circulation in the EU market, mainly because it did not generate enough knowledge on their uses and specific problems.[62] To overcome these limitations, REACH subjects all chemicals to registration, evaluation and requires the most dangerous ones to go through a new authorization procedure. Registration involves a duty on the industry to compile data and assess the risks of their chemicals through a 'dossier' that is then submitted to the ECHA (a very complicated, expensive and demanding process). In the subsequent 'evaluation' stage, the ECHA checks the quality of the registration dossiers submitted by the industry and proposes corrections where necessary. Finally, the new authorization procedure is a more aggressive regulatory stage, which can ultimately lead

[59] *Ibidem*, p. 58
[60] Regulation (EC) No 1907/2006 of the European Parliament and of the Council, *OJ L 396, 30.12.2006, p. 1–849*
[61] *Ibidem*
[62] 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

to the banning of dangerous chemicals. EU authorization is not a 'one-off' decision, however. It is a gradual process which begins with the identification and prioritization of chemicals for authorization. 'Authorization' also involves a socio-economic assessment of the targeted products. The ECHA is asked to balance the environmental and public health risks of chemicals against the wider socio-economic advantages that are involved in their uses around Europe.

The REACH system is not working as expected and this is leading to new institutional problems. First, the registration system has proved incredibly complicated administratively and has failed to generate the desired level and quality of data on the substances.[63] The check on the industry registrations has also proved difficult because the ECHA lacks the internal resources to do this properly (and it is an immense task). The Agency is highly dependent on the willingness and capacity of the industry to provide the substance data and it has limited powers to police compliance. The result has been a distortion of the REACH procedures. The EU authorisation procedure, which was meant to be an exceptional measure for the most dangerous chemicals, is being used as a wider instrument to acquire more data on substances in cases where risk uncertainty persists. This is not without important consequences. The EU authorization procedure is a very demanding process for the industry in terms of risk data collection and analysis (including the socio-economic factors) and it threatens with a marketing ban if a strong case has not been made by the company in favor of authorisation. The extensive use of the authorisation procedure for fact-finding purposes may represent a significant burden for small and medium enterprises and it imposes obligations on third-parties (i.e. downstream users of the substances) which cannot be blamed for registration failures. The regulatory dynamic raises a risk of abuse of regulatory power and this is hardly an appropriate way to generally address the problems of an ineffective regulatory regime.

V. Principles of fluid administrative law

In view of the dynamic, capacity-related dysfunctions, additional external and formal constraints on EU regulatory agencies will hardly help to improve things. Such

[63] Supra 57, [L. Barroso], p. 77-78

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. Those 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. There is a contrast here with a more static conception of administrative law. 'Static administrative law' associates formal administrative procedures and the dynamics emerging from the latter, assumes that administrative law problems can be understood *a priori* and that we have the instruments necessary to anticipate the risks of particular institutional arrangements, and underplays the process of EU administrative integration as something that generates new institutional concerns related to the workings of the public administration. The resonance of static administrative law helps explain the current insistence on more judicial, political or parliamentary controls on EU agencies.

The alternative, principles of fluid administrative law, seek to identify and inject dynamic controls in the new administrative state. In other areas of EU governance, such controls exist. In EU comitology, for example, 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' which emerge from the operation of those systems.[64] 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 consequently distinguish between (and develop) four principles: internal process, external justification, commitment to pluralism and policy effectiveness. A flexible compliance of EU regulatory agencies with those four principles would improve the quality of governance while promoting important administrative law concerns.

The principle of *internal process* 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. Internal procedures

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

include norms on how decisions are adopted and the requirements of the agencies in that context. There are a number of reasons why it is desirable that agencies stick to their internal procedures. First, these ensure that a number of controls within the decision-making process are maintained. They also provide safeguards for third parties as to how institutional decisions are taken.[65] Internal process provides, in addition, more material for external checks on the administration. The commitment to a particular institutional order illuminates external actors on what the concerns and alternatives were. The dynamic 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 institutional practice of the agencies may escape some of these restrictions and create new problems.

Secondly, the principle of *external justification* places a duty on the new administrative state to give reasons for its decisions. External justification imposes requirements on EU regulatory agencies to explain why they have done things in a certain way, to be questioned by those affected by public power and to be responsible for the reasons which are offered. That then allows external actors or patrols to understand the institution and its motives in a given case, and it enables litigation.[66] Moreover, external justification also establishes a dynamic relationship between the new administrative state and those to whom reasons have been given. External justification will therefore be important if it becomes an instrument of dialogue between the new administrative state and those affected by it. The EU legal system does little to require such an effort from the authorities, however. The case-law holds a very narrow understanding of the duty to give reasons under EU law.[67] 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 between the new administrative state and those with whom it interacts.[68]

Thirdly, the principle of '*commitment to pluralism*' (or duty to take on board diffuse interests) considers who the new administrative state interacts with, whose views

[65] H. P. Nehl, *Principles of Administrative Procedure in EC Law*, Hart Publishing, 1999, p. 22
[66] 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
[67] Case C-113/00 *Spain v Commission* , ECR 2002 I-07601
[68] Supra 3, [Chalmers et al, 2010], p. 377

are being considered 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 are ignored. An effort to accommodate diffuse interests also makes institutions more internally reflexive. 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. Some EU regulatory agencies include Stakeholder Groups within their processes so as to ensure the representation of diffuse interests (e.g. consumers, small and medium enterprises, users of the products) in decision-making. The existence of those structures, the increasing provision for consultation with them and even their growing activism might not be sufficient, however, to ensure that the EU agencies in fact take on board a wider range of interests.

Finally, the principle of *securing policy effectiveness* seeks to protect the institutional ability of the public administration to pursue relevant policy goals. EU regulatory agencies have been created to achieve certain policy objectives (the 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, etc). 'Securing policy effectiveness' emphasizes that it is important that agencies be given the instruments and resources to carry out the tasks which they were created to perform. Internal capacity constraints can be an obstacle in that context. This fluid principle also 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 necessary tools to fulfill EU regulatory programmes and initiatives.[69] Where serious obstacles to the accomplishment of the central objectives of an agency are present, 'securing policy effectiveness' would stress that the structure, powers and *modus operandi* of that body should be reassessed. This fluid principle therefore draws attention to the reform of EU agencies' procedures and

[69] On the idea that the purpose of a liberal constitutional order does not only seek to restrict public interference in private affairs but also 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

suggests that there may be creative ways of doing better with the same level of public resources.

VI. New administrative controls and regulatory agencies

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 dysfunctions to be 'attacked', but rather a plurality of dynamics and risks. As such, the solution to each agency's problem should be designed in accordance with its particular features and challenges. The link between the different controls and proposals is provided by the existence of constant principles, as considered above.

(i) 'Internal process' and the European Ombudsman

The European Medicines Agency (EMA), considered above, highlighted risks of institutional decentralization and strong reliance on national outsourcing. The Rapporteur is too powerful and the European peer reviews do not work. The internal process of the EMA, which reserves a role for the CHMP in the control of the Rapporteur's scientific assessments, has been transformed and 'checks and balances' within the system are diluted. The problems of the European Medicines Agency are particularly worrying from the point of view of the internal process and external justification principles. It is suggested that dynamic controls be performed via the European Ombudsman (EO). While the EO is a "modest entity" (8 million Euros of budget and approximately 60 staff), the soft and more informal nature of its mandate can also be an advantage in the supervision of supranational regulatory systems.[70] Unlike Courts, the EO allows for "free and easy access for the citizen" and relies on "moral authority" and "cogency of reasoning" to be effective."[71] The Ombudsman also has the advantage of doing away with strict standing rules and is relatively swift.[72] The reduction in formalism means that the intervention of the Ombudsman ensures, at least,

[70] C. Harlow and R. Rawlings, *Promoting Accountability in Multilevel Governance: A Network Approach*, European Law Journal, Vol. 13, No. 4, 2007, p. 556
[71] 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
[72] Supra 70, [Harlow and Rawlings, 2007], p. 555

that the target EU body provides reasons for its approach or decisions.[73] The interaction of the Ombudsman with the EMA scientific assessment process might place greater pressure on the Rapporteur to justify herself while providing an external incentive for the scientific committee to intensify its review if a problem appears to exist. The EU regulatory system might also need to look for stricter rules on the outsourcing of tasks to national authorities, namely to prevent the risk of 'capture' by the regulated industry. A recent report of the European Court of Auditors concluded that the outsourcing of regulatory tasks to the national competent authorities is not being followed by adequate conflict of interest constraints on the experts that work for the European system, and gave the EMA as an example of this problem.[74] The same report also warns about lack of controls on these experts and is wary about their "past or present connections to the industry (such as employment, research funding, etc.)."[75]

(ii) Insufficient resources and external patrols

Other EU agencies are less reliant on national outsourcing and more dependent on the collaboration of the industry for the regulatory policy to work. In sectors where the regulated products are particularly complicated and dynamic (in the sense that knowing about their risks requires ongoing supervision and local involvement), an active involvement of the industry can be necessary to ensure that the regulatory regime is effective. The internal capacity constraints of EU agencies may put them in a difficult position in dealings with industry. The European Chemicals Agency (ECHA) is a case in point. The failures of the registration system for chemicals and the lack of resources of the Agency to police the way companies are providing the data on their substances has led to ineffective regulation and internal administrative distortions. The new authorisation procedure, which was meant to target the most dangerous chemical substances in the EU market, has acquired a more expansive role and is strongly relied on for fact-finding purposes. As a consequence, the center of EU agency power has moved from the (final) scientific opinion to the previous and intermediate stages where products are selected for authorisation. That dynamic is problematic and it escapes

[73] Supra 41, [Busuioc, 2010], p. 198-199
[74] European Court of Auditors, Special Report No. 15, 2012, 'Management of Conflict of Interest in Selected EU Agencies', p. 11-12
[75] *Ibidem*

formal controls on the expertise. The first important thing would appear to be the integration other external capacities in the system. The ECHA could, in particular, rely on environmental NGOs to serve as patrols and support it in the review of the industry registration dossiers and the missing data.[76] In addition, on the basis of an ECHA opinion, the Commission could be given the power to fine companies which have consistently failed to provide the data or shown lack of a credible effort to acquire and supply that information.[77] The solution conforms well to 'policy effectiveness' by increasing the pressure on the industry to fulfill its obligations. If that happens, the internal process would also have been restored. The use of the authorisation procedure would then only be used if no other viable alternative could be found.

(iii) Structuring dynamic controls over time: a new EU agency?

The fact that we need clearly different controls in each EU regulatory agency shows how fluid administrative law has to become in order to deal with the problems of the new administrative state. The heterogeneity of solutions then raises an issue about institutional design (i.e. how to organize a decentralized model of administrative law). The Regulations establishing EU regulatory agencies provide for a review of these bodies after a certain period (usually three years but it may be more).[78] The review processes of the agencies provide a good opportunity to indentify the challenges which they raise and to look for the appropriate corrections. To pursue this task effectively, however, new institutional capacities might be needed. Currently, the shape of the review process of the agencies varies across sectors and it has a narrow focus on the effectiveness of the regulatory regime. The European Medicines Agency, for example, is reviewed by the Commission, while the European Chemicals Agency performs its own review.[79] The use of a set of constant principles to coordinate the agencies could benefit if a new EU body was created to review their operations and make proposals on administrative controls on the basis of the said principles. A new meta-agency would not have to be a large or

[76] Supra 57, [L. Barroso], p. 69
[77] *Ibidem*, p. 90-91
[78] For example: 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*. See Article 62.
[79] 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*

expansive structure, and it could rely on contributions from national officials. It would avoid the dispersal of actors and forums for account giving by setting up an institutional system with adequate instruments to learn about the problems of the new administrative state and greater capacity to inject controls on its work.

The introduction of a meta-EU agency to police the regulatory agencies on the basis of common principles would also highlight that the advantages and risks of European administrative integration deserve to be read on its own terms. European regulatory agencies are responding to new kinds of transnational challenges, and do that through novel forms of inter-national and intra-sector communication. Those constellations of power may generate benefits to the EU, but they also imply risks for administrative law and controls. Important legal principles are being challenged by new institutional pressures and imbalances, and administrative law should adapt itself to these developments without letting go of its central concerns. The lack of homogenous EU agencies may be something we can work with if the administrative implications of that phenomenon are understood and adequate solutions found. A new meta-agency would be a good way to reconcile the dynamism of the EU administrative state with legal concerns which should not go away. The result would hopefully then be the emergence of more adequate and effective checks and balances within the European administrative system.

Conclusion

European regulation has undergone significant transformations during the last fifteen to twenty years. The new administrative state, where regulatory agencies are important, involves a strong commitment to a common European voice of 'science' and excellent technical knowledge. While the formal authority of some of the most powerful EU agencies rests with the provision of 'expert opinions' to the Commission, the regulatory state then imposes on the Commission a duty to follow those recommendations unless it can come up with different, but equally relevant, scientific arguments to support its own solutions. The modern administrative state has also equipped newer EU agencies with some strong and direct instruments of market intervention and operational powers in their respective areas of activity. The connection between the EU system and the

regulation of particularly fluid and complex products is increasing and the agencies are important in that they provide the capacities to meet the new challenges.

The growth of EU regulatory agencies has led to calls for increased controls on them. Judicial review opportunities of EU agency acts have been provided by the Lisbon Treaty and proposals are being made to strengthen the parliamentary checks as well. The spreading of sub-administrative actors and their growing impact on areas of social significance has generated a European response aiming to reconcile that underworld with a stronger political and judicial authority through strict reviews on its operation. Meanwhile, the new administrative state involves a set of challenges and problems of its own. It does not set up large and concentrated regulatory capacities, but only equips the agencies with a common space for the coordination of national actors (experts), and between the latter and market participants. The dependence on national bodies to perform the regulatory tasks may allow those players to exert excessive influence and benefit particular constituencies. The internal checks on the 'European' expertise are also rendered more difficult by the fragmentation of actors and unpredictable search for regulatory capacities. Another danger is the exaggerated reliance on the industry in highly dynamic sectors of the economy and the associated difficulties in terms of pluralism and policy effectiveness. Overall, what emerges is a new administrative state where the central problems are very dynamic and capacity-related. It is difficult to see how highly liquid and variable institutional risks might be contained by strengthening an external and formal constraint on the administration.

The dynamic coordination of EU regulatory agencies could otherwise be ensured through a set of constant legal principles. On the basis on those principles, an effort would then have to be made to introduce adequate controls on the public administration. Instead of imposing a rigid and horizontal check on the operation of the agencies, the common principles should be applied flexibly in each sector/agency, thereby allowing for heterogeneous solutions based on specific problems. The advantage of a fluid administrative law is that it connects much more strongly to the nature of the new EU administrative state while it ensures respect for important legal principles and values. Moreover, since a deeper understanding of the administrative state is required to structure new and effective controls on its operations, the creation a new EU meta-

agency to uphold the principles could be envisioned. That body could then be used to make proposals on new administrative controls on the basis of a coherent legal strategy.

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