Journal of European Integration
Publication details, including instructions for authors and subscription information:
http://www.informaworld.com/smpp/title~content=t713393849

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Susana Borrás [a]; Charalampos Koutalakis [b]; Frank Wendler [c]
[a] Center for Business and Politics, Copenhagen Business School, Frederiksberg, Denmark
[b] Department of Political Science and Public Administration, University of Athens, Athens, Greece
[c] Faculty of Law, University of Maastricht, Maastricht, The Netherlands

Online Publication Date: 01 December 2007
To cite this Article: Borrás, Susana, Koutalakis, Charalampos and Wendler, Frank (2007) 'European Agencies and Input Legitimacy: EFSA, EMeA and EPO in the Post-Delegation Phase', Journal of European Integration, 29:5, 583 - 600
To link to this article: DOI: 10.1080/07036330701694899
URL: http://dx.doi.org/10.1080/07036330701694899

European Integration
Vol. 29, No. 5, 583–600, December 2007

ARTICLE

European Agencies and Input Legitimacy: EFSA, EMeA and EPO in the Post-Delegation Phase

SUSANA BORRÁS*, CHARALAMPOS KOUTALAKIS** & FRANK WENDLER†

**Center for Business and Politics, Copenhagen Business School, Frederiksberg, Denmark*
***Department of Political Science and Public Administration, University of Athens, Athens, Greece, †Faculty of Law, University of Maastricht, Maastricht, The Netherlands*

ABSTRACT Most studies about the role of independent agencies in the European context focus on the driving forces that condition the incentives of political actors to delegate policy-making competencies, and that influence the agency design and the consequences of delegation for democratic control. However interesting, these studies often disregard the question of the legitimacy of the agencies in the post-delegation phase. This article aims at redressing this important blind spot in the current literature by highlighting the need for procedural input-legitimacy at the stage of agency operation. It argues that procedural credibility is a fundamental property that explains the need for an increased interaction between agencies and stakeholders at the post-delegation stage. The article examines three prominent cases of agencies in Europe — the European Food Safety Authority, the European Medicines Agency and the European Patent Office — in order to assess the extent to which the institutionalization of stakeholder networks facilitate credible knowledge that enhances their input and output legitimacy. The concluding remarks bring these results under the general perspective of democracy and new modes of governance in the EU.

KEY WORDS: EU agencies, legitimacy, stakeholder involvement, EFSA, EMeA, EPO

Introduction

During the past few decades, there has been a significant growth in the number of supranational independent regulatory agencies (IRAs). To a large

Correspondence Address: Susana Borrás, International Center for Business and Politics, Copenhagen Business School, Steen Blichers Vej 22, 2000 Frederiksberg, Denmark. Email: borras.cbp@cbs.dk

ISSN 0703–6337 Print/ISSN 1477–2280 Online/07/050583-18 © 2007 Taylor & Francis
DOI: 10.1080/07036330701694899

extent, these agencies can be regarded as new modes of governance not only because in organizational terms they are largely decentralized and autonomous from central executive power but also due to their operational modes that often provide an essential interface between the public and the private spheres in the implementation of specific market-related allocative decisions. In the EU there are currently twenty-nine 'community agencies', twenty-three of which are located in the first pillar. In contrast to national traditions, none of these agencies has truly regulatory competences. Rather, they perform specialized advisory tasks, formulating non-binding opinions and soft policy instruments such as best manufacturing practices and regulatory information addressed to national authorities, firms and consumers. These instruments have crucial normative authority for the subsequent stages of decision making at the comitology level, especially in policy areas characterized by high levels of technical and scientific expertise, uncertainty and complexity of goals. Beyond the EU, there is also a growing number of IRAs and standardization bodies. International bodies, such as the European Patent Office (EPO), perform regulatory tasks explicitly linked to the creation of a single market.

Most studies about the role of IRAs focus on the conditions for the establishment of delegation. However interesting, these studies have conceived too narrowly the question of their legitimacy in the post-delegation phase, reducing them mainly to questions of principal's control. In particular, current discussions within the principal–agent approach reveal that there are doubts about the objectivity of functional pressures driving the creation of agencies, and that the establishment of agencies is contingent upon socially constructed perceptions and legitimacy beliefs, institutional path dependency, and actor-related arguments (constellations, resources, knowledge). This leads to the assumption that the daily operation of agencies, and their effectiveness and legitimacy, can hardly be decoupled from their social and political environment.

This article examines the conditions under which IRAs enjoy input and output legitimacy in the post-delegation phase. It is argued that in complex and socially contested regulatory areas, the post-delegation efficiency and effectiveness of those agencies is largely contingent upon their capacity to institutionalize participatory regulatory networks in order to secure input legitimacy and generate trust among major stakeholders. The extent to which European agencies succeed to establish such input-legitimacy, however, is still a question of empirical research. This gap in the existing research is addressed by developing the notion of 'credible procedures' as a criterion to evaluate the patterns of exchanges between IRAs with stakeholders in their day-to-day operation. The article presents evidence from three prominent case studies in Europe, in the regulation of food safety (European Food Safety Authority, EFSA), medicines (the European Medicines Agency, EmeA) and patents (EPO). The article proceeds as follows. The next two sections provide a critical review of the existing literature in the field, pointing at important analytical blind spots. The fourth section introduces the notion of 'credible procedures' and develops some assumptions about the

importance of stakeholders' participation and consultation for generating such a type of legitimacy. The subsequent three sections are devoted to the empirical analysis. The concluding remarks reflect upon these empirical results and elaborate on their theoretical consequences for the issue of democracy and new modes of governance.

Agency Creation and Agency Operation: the Limitations of Principal–Agent Approaches

It is a typical explanatory pattern of principal–agent approaches to derive the creation of IRAs from quasi-objective, technical-scientific and regulatory requirements occurring in modern societies. This school assumes that the intensity of these functional pressures determines principals' preferences on the institutional design of IRAs. The higher the functional pressures experienced by principals in a given policy area or country, the more powers they will delegate to IRAs and the weaker will be the control mechanisms. Therefore, the principal–agent school concludes that agency design and delegated powers reflect the distribution of relatively stable preferences between principals, and that changes in the distribution of preferences with the addition of new actors generate variations between different IRAs over time. For example, it is argued that in the EU, the addition of the European Parliament as a political principal on its own right has contributed to the emergence of more participatory and transparent agencies, such as the EFSA, compared to the first generation of IRAs that are dominated by national government representatives (Kelemen 2002).

Bureaucratic politics offer significant insights to the process of agency design. However, they fail to conceptualize synchronic variations in the role and regulatory functions of IRAs in different policy areas. Elected officials often experience identical functional pressures from different regulatory policy areas but agency design and the timing of delegation differ considerably across different countries and policy areas (Thatcher 2002, Thatcher and Stone Sweet 2002). Challenges to the principal–agent framework draw on sociological and historical strands of new institutionalism. The first emphasize that delegation to IRAs as a choice is socially constructed (Thatcher and Stone Sweet 2002, p. 12). Elected officials often favour delegation even in the absence of significant functional pressures. In regulatory sectors such as telecommunications, transport, competition and broadcasting, knowledge-based elites, professional networks and international organizations help to diffuse delegation to IRAs as the dominant paradigm in solving collecting action problems. Furthermore, historical institutionalists emphasize that policy-specific factors mediate functional pressures and affect both the momentum for the establishment of IRAs and their institutional design.

There is growing evidence that the political clout of IRAs to fulfil their mandate cannot be narrowly derived from their formal mandate or critical junctures in the agencies operation, but is at least partly dependent on the interaction with their regulatory environment and relevant social actors. The

ability of non-state actors to provide essential resources such as technical knowledge and engineer consensual policy making are crucial factors determining post-delegation efficiency and effectiveness of IRAs. In turn, the latter play a crucial role in structuring their regulatory environment through the institutionalization of credible procedures and networks of interaction with the stakeholder community. Pre-existing convergence of preferences between resourceful actors and the likelihood of consensual regulatory outcomes reduce the risk of 'agency losses' i.e. the gradual emergence of divergent preferences and agendas from the ones initially delegated by the principals in the policy area.

Taken together, the arguments elaborated here cast doubt on the conceptualization of agencies as quasi-automatic functional responses to objectively given external pressures or increasing complexity. Instead, this article depicts agencies as political creations that are contingent on socially constructed views and legitimacy beliefs, institutional path dependencies, and actor preferences and constellations. Furthermore, it is argued that approaches focused on the question of agency design overlook important elements (and challenges) of the daily operation of agencies, such as the creation of accountability structures, input-legitimacy and credibility of knowledge.

Legitimacy of Independent Agencies: Input and Output Perspectives

The most commonly used justification for IRAs is based on elements of output-legitimacy and the substantial credibility of policy making. Like other non-majoritarian institutions, agencies are generally expected to fulfil regulatory goals in the public interest (such as rights protection, enforcement of competition rules, or consumer protection) better than central government institutions because they are isolated from the direct scrutiny of voters, changes in government and the influence of powerful pressure groups (Majone 2000, Majone 2005, Thatcher and Stone Sweet 2002, pp. 18ff.). In the context of EU governance, the creation of agencies is favoured as a tool for securing a regulatory commitment by the member states in the face of a growing politicization of the Commission, and Community policy making (Majone and Everson 2001, pp. 132ff.). This argument is also central to the reasoning of the Commission's operating framework for EU regulatory agencies: "The main advantage of using the agencies is that their decisions are based on purely technical evaluations of very high quality and are not influenced by political or contingent considerations" (Commission of the European Communities 2002, p. 5). Against this background, it is argued that agencies provide the necessary expertise and technical knowledge to handle complex tasks of regulation increase transparency, reduce transaction costs and provide more effective solutions in policy making, allowing the Commission to concentrate on its core task of political guidance (Vos 2005, pp. 11ff.).

Whereas the notion of 'regulatory state' may present an intellectually coherent model to explain the emergence of delegation of regulatory competences to IRAs, an empirical problem in relation to the existing EU agencies is that they lack formal regulatory competences. Countering these critical

views, it has been suggested that EU agencies, even in their advisory role, assume an important function for the conduct of European governance not through immediate policy-making outputs, but through their integrative function as nodal points of wider regulatory networks that include national authorities, scientific communities and, not least, private enterprises and civil society organizations (Dehousse 1997, pp. 254–259). It has been argued in the literature that the systematic inclusion of public and private stakeholders from multiple levels of government in formal and informal transnational networks is often accompanied by decision-making rules and processes that favour the dynamic forging of consensus and the exchange of knowledge (Eberlein and Grande 2005, pp. 90ff.). Especially in fields of regulation with a high need for coordination between national authorities and contested knowledge claims within the scientific community, the achievement of output-legitimacy through effective regulation may be dependent on the integrative and consensus-orientated function of regulatory networks on the input-side of the policy-making process (Skogstad 2003, pp. 330ff.).

By contrast, output-based approaches deal with the problem of input legitimacy either in the framework of initial institutional design or take for granted that the institutionalization of IRAs fosters the emergence of a strong political and ideological consensus on the substantial and procedural approaches to regulation. The Commission has deliberately advocated an operating framework for IRAs that "authorises them to intervene only in areas where a single public interest predominates and in areas where the agencies are not called upon to arbitrate on conflicting public interests" (Commission of the European Communities 2002, p. 8). However, uncertainty and hidden distributive effects of regulation between winners and losers may generate contested views between the various stakeholders and the public.

For this reason, this article questions whether the assumption of a single public interest can be assumed in all cases. Whereas it may be acceptable in strongly technical fields of regulation where costs and benefits are distributed equally, it appears much more doubtful in politically contested fields like GMO authorization, medicines or other fields of risk governance, in which civil society groups have openly attacked the regulatory approach of the EU. This example dramatically illustrates the central importance of the *credibility* and *legitimacy* of knowledge claims proposed by IRAs, and the dependence of output-related legitimacy on the creation of trust and consensus on the input-side of regulatory policy making. However, the actual performance of stakeholder networks and the extent to which they contribute to the development of trust between IRAs and the wider society is still largely a matter of empirical research.

Credible Procedures, Democratic Legitimacy and Network Governance

By adopting a process-orientated perspective and seeking to identify the conditions under which agencies might enjoy input legitimacy, this article seeks to contribute to current debates regarding the credibility and legitimacy of scientific involvement into the policy process, and the challenges to democratic

governance associated with the role of experts in contemporary political systems. Starting with the first, the wider social and political context where IRAs operate has changed dramatically with the advent of strong popular contestation in relation to scientific and technical knowledge, in issues like bioethics, GMOs, medicines, software patents or food safety, just to name a few. Social contestation reflects several interrelated aspects, such as the growing social awareness about the limits of scientific knowledge and of pervasive scientific uncertainty upon which some political decisions are often made (Guston 2000, p. 25). It also mirrors the increased production of scientific knowledge outside the conventional channels of scientific institutions (typically by non-governmental organizations like patient associations, enterprises, consumers or environmentalists) which challenges official scientific explanations (Nowotny *et al.* 2001). Furthermore, social contestation and distrust has been increased by scandals in Europe regarding mismanagement and misinformation of scientific knowledge by public authorities in cases such as the 'mad cow disease' or the 'dioxine' crises.

There is a growing acknowledgement among scholars that the principles and practices of liberal democracies are challenged and transformed by the increased role of experts in decision making (Fischer 1990). The role of experts in a democratic political system touches upon the principles of equality among citizens and the ideals of representation upon which the norms of liberal democracy are based (Turner 2003, p. 23). Moreover, it has an enormous impact on the normative and political authority of contemporary public administration, upon which the principles of executive delegation in liberal democracies are ultimately based. These arguments particularly relate to IRAs, which are highly decentralized and rely heavily on scientific experts to perform their tasks. Taken together, the growing popular discontent in Europe has been associated with a crisis of the Weberian model of bureaucratic rationality on scientific-technical issues, since the decisions of experts regarding what is adequate scientific knowledge and what constitutes an acceptable risk are no longer popularly endorsed (Weale 2002).

Therefore, addressing the legitimacy problems of regulatory policy making involves tackling the controversies at the level where they emerge, namely, the stakeholder level. It is this level that has been normatively associated with the need to 'democratize expertise', by extending the modes and channels for popular consultation as a way of guaranteeing social representation and delineating the role of experts (Liberatore and Funtowicz 2003, p. 149, Weale 2002, Jasanoff, 2005, p. 45). Other authors suggest the need to go beyond popular consultation and create mechanisms that allow development of a true co-production of knowledge between experts and stakeholders, so as to secure that knowledge employed by IRAs is not only scientifically sound but also "socially robust" (Nowotny 2003, Callon *et al.* 2001, p. 34). Both approaches point to the significance of *procedures* as crucial determinants of the nature of exchanges between expert bodies and stakeholder communities with the aim at generating trust.

The daily praxis of European agencies comprises different forms of interaction with stakeholders articulated in governance networks. Agencies have

been conceptualized not as isolated from political cleavages but as nodal points of regulatory networks that include both public and private actors (Dehousse 1997, p. 251, Eberlein and Grande 2005, p. 93). Regulatory networks take the form of more or less formalized channels of consultation and participation, are loosely or tightly coupled, and tend to be created through time in relation to specific needs of the agency. In this context, it is argued that these networks might have the potential to be an essential source for linking the input side and the output side of legitimacy of the IRAs' daily operations.

However, the extent to which and the conditions under which these networks of interactions are able to generate sustainable input and output legitimacy is a matter of empirical research (May 2007). Whereas previous scholars have assumed the existence of consensual political dynamics in these networks of stakeholders, the present study does not share such assumptions, since political processes of contestation and debate within participatory networks of stakeholders might well result in both trust and consensus but also stalemate and crisis.

To embark on such an empirical investigation, the term 'credible procedures' is introduced, defined as an evaluative term for the involvement of stakeholders consisting of three critical elements: First, the structure of emergent stakeholder networks, i.e. the patterns of inclusion and exclusion of affected interests, the degree of density of their interactions and the forms of coordination that structure regulatory networks operating under the auspices of IRAs. Second, the logic of interactions within these networks with emphasis on the contents and the extent to which there is a culture of consensus-seeking or of aggregative-debate processes in the interaction between the network of stakeholders and the IRA. Finally, the socio-economic context in which interactions between stakeholders and IRAs take place in order to assess whether network interactions reflect and accommodate the main societal concerns. Taken together, these network properties indicate the emergence of inclusive procedures that are able to generate credibility and trust in expert opinions of IRAs.

In order to assess the extent to which the institutionalization of stakeholder networks contributes to the gradual generation of credible knowledge that feeds into the work of regulatory networks and generates input and output legitimacy, the article examines three prominent cases of agencies in Europe, the EFSA, the EMeA and the EPO. These agencies appear as particularly relevant case studies for the investigation of these questions, as they operate in highly technical areas, which have been subject to substantial societal debate during the past decade, not least about the role of the agencies themselves.

The European Food Safety Authority: Re-building Legitimacy and Credibility?

The issue of credibility and trust appears as particularly essential in the case of EFSA. Following on the loss of confidence in regulatory institutions

caused by the BSE crisis, this relatively new agency was created as part of a general revision of the EU framework of food safety regulation through the adoption of the 2002 'General Food Law'[1] (GFL). The regulation defines the role of EFSA mainly as the responsibility of issuing scientific opinions and providing scientific and technical support to the Commission (i.e. tasks of risk assessment), whereas all functions of evaluating socio-economic concerns and political decision making (i.e. tasks of risk management) remain with the Commission and its interaction with the member states through the comitology procedure. Emphasizing the principles of independence and scientific excellence of EFSA, the GFL therefore establishes an entirely output-based rationale for its operation, to provide the scientific basis for the adoption of Community measures with the objective of contributing to "a high level of protection of human life and health" (Article 22, 3 GFL). This objective is combined with various requirements of transparency (*inter alia*, with regard to the publication of session documents and opinions, and the declaration of interests of members of the Scientific Panels), and provisions to guarantee the involvement of the so-called "stakeholders", i.e. the key interest organizations representing consumers and other interests throughout the food chain. In this regard, three of the fourteen members of the EFSA Management Board are required to have their background in such organizations, and the GFL includes a requirement for EFSA to develop "effective contacts" with all interested parties (Article 42 GFL).

Corresponding to its mandate, EFSA has sought to establish a variety of involvement procedures with a wide variety of stakeholder groups. Consultations take place mainly on three levels: First, EFSA holds online public consultations and issues requests for data through its website on a number of scientific subjects, especially in relation to the risk assessment of pesticides, additives and biological hazards. Secondly, technical meetings on specific issues have been organized on an *ad hoc* basis, including a meeting with environmentalist NGOs on the risk assessment of genetically modified organisms. Further consultations with scientists and stakeholders are also organized regularly through the Scientific Colloquia and the Annual Colloquia of EFSA. Thirdly, following on the demands of many interest groups for more structured and transparent forms of consultation, a 'Stakeholder Consultative Platform' was established which has met more or less on a half-yearly basis since its inauguration in October 2005. This platform comprises a wide range of interests, including groups such as Friends of the Earth and Greenpeace who are known for their very critical stance towards the risk assessment of GMOs by EFSA. The Platform acts as an advisory group to the EFSA Executive Director in relation to a broad range of 'horizontal' issues, concerning the agency's risk assessment policy (i.e. its work programme, methodological questions, and feedback on the effectiveness of policies by stakeholders). This Platform has debated on a number of general issues in relation to the work of EFSA, for example the evaluation report on EFSA, the question of whether to establish fees for authorizations, the improvement of the interface with member states and the discussion of emerging risks. Most recently, members of the Stakeholder Platform also

established working groups on the transparency of risk assessment, mirroring a working group of the Scientific Committee of EFSA with a similar mandate, and on criteria for public consultation. Therefore, a variety of involvement procedures has been established both on very technical and case-specific as well as more general procedural and methodological questions, giving rise to a dense interaction between EFSA and its key stakeholders. These developments indicate that instead of isolating itself from the wider scientific and societal context, EFSA is actively seeking input and comments by its stakeholders in a structured and transparent way.

Concerning the credibility of involvement procedures, it can be concluded that the structure of consultation procedures at EFSA is relatively open (involving a wide range of organizations at the level of the Stakeholder Platform and allowing for inputs from a wide range of actors through online consultations) and stakeholder-orientated (as indicated by the fact that the Platform is chaired by stakeholder representatives who take an active influence on the agenda). Minutes of the meetings so far indicate that the form of interaction mainly is aggregative, implying that views and priorities of both EFSA and the stakeholders are made known, information is exchanged and forthcoming tasks and priorities are discussed, whereas the engagement in deliberative procedures and the creation of consensus is possible only to a limited degree. These two points can be taken as an indication of an attempt by EFSA to engage openly and transparently in a debate with its main stakeholders.

A more ambivalent judgement has to be made with regard to the socio-political context of the debate between stakeholders and EFSA. In this regard, a crucial point is that in accordance with the mandate of EFSA, both the case-specific consultations and debates within the Stakeholder Platform are in principle limited to 'scientific' issues, thus excluding debates about the wider socio-political implications of risks. The credibility of these involvement procedures therefore appears dependent at least to some extent on the separation between the scientific assessment of risks and their political evaluation and handling through risk management measures. Regulatory practice, however, has revealed that although this separation is broadly accepted in principle, it remains difficult to establish in practice, giving rise to interaction effects and 'grey zones' between risk assessment and management (Vos and Wendler 2006, pp. 119ff.).

A striking recent example of such an interaction can be found in the authorization of genetically modified food, in which EFSA assumes the role of the main risk assessor in a centralized European authorization procedure. In this field, tensions have arisen on the adoption of 'safeguard measures' in some member states, banning the entry on the market of products in spite of their authorization through the Commission on the grounds of 'remaining scientific uncertainty'. Especially through this link between political measures and the issue of scientific uncertainty, the debate has spilled over into the realm of risk assessment to question the scientific and methodological approaches taken by EFSA. Following on a debate in the Environmental Council of March 2006, which criticized the lack of transparency of risk

assessment by EFSA and its failure to take into account the concerns of member states, an announcement was made by the Commission to adopt a new approach towards the authorization of GM products, calling directly on EFSA to consider more comprehensively the scientific concerns of member states and to give better reasons why they were not considered.[2] Against the background of the doctrine of a strict separation of risk assessment and management, this may be considered a rather drastic intervention, giving rise to various recent consultations of EFSA with member state experts on its risk assessment policy on GMOs, and discussions within EFSA's Advisory Forum how to develop a new strategy of scientific cooperation with the member states.[3]

While this example clearly goes beyond the remit of stakeholder consultation, it is used here to indicate its limitations: As the GMO case illustrates, it remains questionable how far stakeholder consultation by EFSA can address concerns from the wider institutional and political context of EFSA's operation, especially questions arising at the 'interface' between the scientific and political components of risk analysis, such as the identification and handling of scientific uncertainty, and elements of socio-political ambiguity which give rise to the social contestation of new products and technologies. In this context, the example also demonstrates the difference between a narrow perspective on agency creation — suggesting a limited, rather technical, and altogether output-orientated role of EFSA — and its actual operation, which is much more concerned with procedural issues such as the handling of feedback from risk managers, and the involvement of concerned stakeholders and member states to establish credibility in the scientific approach taken by EFSA. Both issues demonstrate the relevance of input-legitimacy at the stage of agency operation, particularly in fields in which the objectivity of 'sound science' cannot be taken for granted.

European Medicines Agency: the Silently Networked Agency

Since its creation in 1993, EMeA has been confronted with conflicting expectations and demands emanating from contradictory regulatory objectives of a wide range of affected interests. The agency's creation was viewed as a milestone in the realization of a truly functional internal market for medicines since it was the only decentralized EU body granted with significant regulatory competencies regarding market authorizations of certain medical products. There are currently two procedures for obtaining an EU authorization: the 'centralized procedure' managed by EMeA which is compulsory for biotechnology products and optional for other innovative medicines; and 'mutual recognition', a decentralized procedure where an application approved by any member state's regulatory body is automatically accredited by all other national counter-bodies. EMeA is *de facto*, if not *de jure*, a 'quasi'-decision-making agency as the Commission normally decides upon its recommendations. Member states have the right to send written observations on the draft decisions of the Commission. In order to be effective member states have to demonstrate that an important scientific

issue has escaped the notice of the applicant, the relevant scientific committee of the agency, the agency itself, and/or the Commission. This is considered to be rather unlikely (Everson *et al*. 1999, p. 11).

Market authorization of medicines affects a wide range of interests. Health care considerations related to safety, quality and efficacy of drugs, containing health care costs, competitiveness of pharmaceutical industry and research and development capacity are the fundamental lines along which a wide range of public, private and social actors constellate. National ministries of health care, finance, research and technological development, trade and industry, generic and organic industry associations and individual production and distribution firms, professions such as doctors and pharmacists, health care organizations at the national, regional and local community levels, consumer associations, patient groups and the scientific community breed in a dense network of interactions where scientific expertise and credible knowledge are the key instruments in order to advance their preferable policy outcomes (Permanand and Altenstetter 2004). The systematic coordination of scientific inputs from the variety of affected interests is therefore central in the evaluation and supervision of medical products. However, the systematic involvement of all affected interests in the day-to-day operations of the agency is scarce.

The EU regulatory system for medicines is structured around the principles of decentralization and integration based on a plurality of collaborative arrangements between national authorization agencies that undertake market authorization and post-authorization surveillance. The central node of the network arrangements is EMeA, which undertakes the role of coordinator in the framework of centralized and decentralized authorization procedures. Since its creation, EMeA's formal institutional structures have reflected the imperatives of shared allocation of competencies between multiple national regulatory agencies embedded in highly heterogeneous national health systems. The agency's management board comprises two representatives from each member state's authorization agencies, two from the Commission and two nominated by the European Parliament, while the main technical working group Committee for Proprietary Medicinal Products (CPMP) that undertakes scientific evaluation of medical products is made up of thirty members, two from each member state.

In highly technical regulatory areas, such as pharmaceuticals, characterized by information asymmetries in favour of industrial actors, the lack of participatory structures of all affected interests generates additional barriers to entry for those groups that lack necessary cognitive resources to influence the policy process effectively. The authorization process comprises several formal and informal interactions between the agency and industry that are insulated from the public and other stakeholders. According to current rules, evaluation of authorization dossiers is undertaken by two independent rapporteurs, one nominated by the applicant. A scientific advice review group, comprised of members of the CPMP, assists the industry on how to proceed with the development of medical products and the authorization dossiers submitted to the agency. This is essentially a process of mutual

exchange of information regarding the quality, safety and efficacy of medical products, which leads to preliminary agreements between the agency and individual firms. In this way firms secure success of their authorization applications at an early stage. Although the agency has established rules of avoiding conflicts of interest between evaluators and the industry as well as transparency rules requiring all decisions to be publicly available through press releases and its website, evidence demonstrates that informal exchanges between the industry and individual rapporteurs often leads to preliminary withdrawals of applications by firms seeking to avoid financial turbulences in cases of imminent rejections (Garattini and Bertele 2004, p. 89).

It is therefore not surprising that the issue of improving input legitimacy and securing credible inflows of regulatory information by all affected interests emerges in all critical junctures of the agency's short history. The reform of pharmaceutical legislation in 2004 and the recent eastern enlargement were the most significant challenges that generated conflicting views over the agency's institutional design. During the recent reform of pharmaceutical legislation the Commission and the European Parliament proposed the reduction of national influence over the composition of the agency's management board and the CPMP and the inclusion of non-state actors along the lines of EFSA. Although the Commission's proposal to include patient and consumer representatives on the agency's management board was accepted, participation of industrial actors was opposed rigorously. Although the strong intergovernmental element largely was maintained, recent reforms brought about a stronger emphasis on independent scientific expertise allowing the CPMP to co-opt five additional members to complement the twenty-five existing national representatives.

The 2004 review of pharmaceutical legislation was connected closely with eastern enlargement of the EU. The inclusion of ten new member states with considerably divergent regulatory traditions compared to that of the EU generated friction both to organic and generic industry as well as applicant member states. Pharmaceutical markets in the central eastern region were regulated previously on the basis of process rather than product patents. Therefore, from the outset of pre-accession negotiations the Commission emphasized that on pharmaceutical and chemical products legislative alignment was progressing at a slower pace than expected due to significant diversity of applicant states' regulatory traditions (Commission of the European Commission 1999). From 1 May 2004 the new member states had to upgrade their existing market authorizations according to EU standards. According to EU rules products from new member states need to obtain market authorization or be withdrawn from the market. Therefore, domestic producers had to update authorization dossiers that contain all essential regulatory information and comply with additional requirements to meet EU standards before the date of accession. The central negotiator on behalf of the EU was the Commission, employing the White Paper as a 'route-map' for the implementation of EU pharmaceutical legislation.

Given the lack of experience and expertise of applicant states' regulatory authorities, intergovernmental pre-accession negotiations were largely

ineffective. The Commission, initially in cooperation with the industry, which in general has close relations both with DG Enterprise and the EMeA, undertook a number of initiatives that opened up pre-accession negotiations. These initiatives were facilitated by EMeA, which undertook the role of moderator and arbitrator between national and sectoral specific interests in the framework of a Pan European Regulatory Forum (PERF). PERF is a unique institutional arrangement. It was established as a 'structured partnership' "to help the associated countries fulfil the requirements of the White Paper for Technical Regulations in respect of the pharmaceutical sector" (EMeA 2001, p. 7). PERF included sixty-six working group meetings, a series of secondments and joint visits that facilitated cooperation, discourse and learning between the national regulatory agencies, the industry and EMeA, especially in the most pressing areas of the *acquis*, most notably the update of product dossiers and post-authorization vigilance. This development was supported by two characteristics of the process: first, the discussions were dominated by the technical problems of the candidate countries' regulatory drug agencies, while national interests were effectively insulated from the process; secondly, PERF seems to have reduced the mutual uncertainty among actors, while enhancing efficiency and effectiveness by reducing demands for derogations in the application of the *acquis* in the new member states (Prange and Koutalakis 2005). This rather exceptional case, compared to the official provisions for day-to-day operation of EMeA, demonstrates the merits of novel institutionalized highly inclusive arrangements that facilitate credible scientific inputs through peer reviewing and enable consensual decision making.

The European Patent Office: Dealing with New Times

Established by the European Patent Convention of 1973, the EPO is the oldest of three agencies under study in this article. This office is the centrepiece of the current patent system in Europe, which is fruit of an intergovernmental agreement currently outside the formal boundaries of the EU. The EPO is an agency that grants patents to applicants after a process of careful examination conducted by in-house expert examiners who use a very specific and legally defined set of criteria. The importance of the patent-granting process is that it attributes individual property rights to innovators on specific pieces of knowledge, with the idea that the innovators will consequently exploit that knowledge and will advance innovation processes for the overall benefit of the society and economy. Therefore, patent granting can be seen as a balance act between the private interest of the patent-holder on the one hand, and the social interest of general welfare maximization on the other (Drahos 2005, p. 142).

The EPO is currently under a double pressure. First, during the past decade the number of patent applications has been growing exponentially. This is not just the case for Europe, but also for the USA and Japan, the two other largest patent systems in the world. This patent surge means that the EPO has had to cope with a rapidly growing workload that should not undermine the

quality of its examination procedures and granting decisions. The second pressure has to do with the mounting popular discontent about the decisions of the office in some sensitive areas, particularly in biotechnology and software. Since the mid-1990s groups of citizens and non-governmental organizations have been heatedly questioning the granting praxis of EPO on these areas, claiming that EPO is unjustly expanding the limits of patentability pre-defined by the European Patent Convention. For these groups, the EPO praxis is ethically and economically problematic, since it benefits specific individual economic interests rather than the wide economic and social interest. For the purpose of this article, the latter issue about social pressure needs further consideration. It is particularly important to examine the way in which the EPO has been facing the challenges of this social pressure, a social pressure that is ultimately an expression of a certain loss of social legitimacy.

Since its creation in the 1970s, the EPO has enjoyed a rather silent life. Confined to the world of technical and highly specialized knowledge, few people outside the world of patent attorneys and large firms knew about the existence of the office and its crucial role in the private appropriation and disclosure of knowledge. It is not adventurous to say that the social uneasiness experienced since the 1990s about biotech patents and software patents came as a relative surprise to EPO officials who were not prepared to operate in a wide and politically laden environment, other than the narrow scope of the political discussions among national representatives in its administrative council. For this reason, the way in which the EPO has been responding to these challenges posed by the societal context has been unusually cautious.

When looking at the interactions of the EPO with its external stakeholders one important remark is that the networks that exist today are formed mainly by legal professionals (patent attorneys, patent agents, patent judges and legal scholars), by patenting firms and by national patent experts (typically working at national patent offices). The EPO has developed several fora where these interactions take place formally. Among the most significant ones are SACEPO (Standing Advisory Committee before the EPO — also known as 'patent law committee'), where the EPO meets users from industry, patent attorneys and national officers to discuss patent law issues; EUROTAB, a pan-European group consisting of lawyers (including EPO staff, and Commission, national patent offices) in the patent field; and the European Patent Judges Symposium, organized once a year by the EPO, where all the patent judiciary from Europe, together with US and Japanese representatives meet. Taken at face value, these fora represent specific meeting places for a series of rather thick and dense networks of stakeholders, which in some cases extend beyond Europe (Davis 2002, p. 145). These European networks in and around the EPO tend to be rather homogeneous in the sense that they are formed mostly by users of the system and/or high experts on the area. Hence, these networks have managed to create a distinct and solid epistemic universe about these technical matters, particularly on legal aspects. This homogeneity shows that the networks of stakeholders do not foresee the possibility of including non-experts, politicians or wider

societal groups. In terms of the content of the network interactions, the high level of homogeneity is probably the reason why these networks have developed a culture of consensus seeking, which is articulated mainly through professional processes of legal interpretation. Debates and collective epistemic development take place through the definition and advancement of legal doctrines, which are specific universes of logical meaning, consequence and interpretation in the field of law.

The relationship of EPO with non-expert groups, particularly with non-governmental organizations (typically critical or sceptical about the work of EPO and the patent system at large) and with national and European members of parliament, is a relationship of one-way communication from the EPO. In other words, the communication policy of EPO is defined in an inside-out direction, and not in a way that the agency brings in the qualified views or expressions of wider stakeholders. The systematic under-development of formal channels and of more informal interactions with these wider stakeholders means that the EPO networks (which are mainly of professional nature) are largely detached from the current social pressures. Although the legal professional networks provide an important basis for epistemic development in a very complex area of law, they are none the less badly suited to tackle issues of wider societal concern and to address the partial loss of social legitimacy of the agency. For that matter, the networks that exist today around the EPO do not seem to provide for credible procedures in the sense mentioned above of generating trust in wide social stakeholders (meaning beyond the reduced circle of users and patent professionals). The traditional focus of the EPO on issues of output quality (good quality of patent examination and agility of granting procedures) is necessary, but will not alone be able to face the voices that criticize the unbalanced granting praxis of the agency. For that to be the case, in the future the agency will need to find ways to create credible procedures able to generate wide societal trust by using qualified and competent non-expert knowledge inputs, on the understanding that improving effectiveness goes hand in hand with improving its input legitimacy. The recent project 'Scenarios for the Future' (2005–2007) launched by the EPO gathered qualified interview data from a hundred different stakeholders. The subsequent report identified four possible future scenarios and put substantial emphasis on matters of social legitimacy. Therefore, there are good reasons to believe that this regulatory agency in Europe will devote much attention to these issues in the near future.

Conclusions: Democracy, Legitimacy and Independent Agencies in Europe

This article analyses how IRAs operate in relation to their surrounding societal context. The principal–agency literature so far has focused mainly on agency creation, and on principal's control of the agencies. However, it is argued that more in-depth studies about agency operation and about agency relation with the surrounding context are needed, especially in areas of regulation of a scientific and technical nature and involving a strong degree

of societal contestation. The theoretical part of the article developed the argument that due to the changing social perception of science and the role of experts in policy making, agencies dealing with socially contested science are in need of input-legitimacy and need to establish participatory networks in order to make their scientific assumptions socially and politically robust. Against this background, the case studies try to do two things: (1) they seek to demonstrate the actual need for input-legitimacy and civil society involvement in regulatory procedures involving such agencies; (2) they evaluate emerging networks with regard to the criterion of credible procedures, which is defined as a term comprising the inclusiveness of networks, a deliberative and consensus-seeking logic of interaction, and the recognition of the socio-economic context of regulation.

Regarding the first point, the case studies all point in the same direction, demonstrating a need for procedural legitimacy and involvement, although with different objectives, given their distinct areas of operation. All three agencies were created as independent agencies, though with the difference that EPO is a regulatory agency, whereas EMeA and EFSA are advisory agencies with a powerful and central role that makes them quasi-regulatory. All of them have been suffering important societal and political pressures in different directions in relation to the contested nature of the scientific and technical areas of their operation, and in relation to the agencies' own performance and strategies. Traditional concepts of input legitimacy based on parliamentary control remain difficult in such inter- and supranational contexts and in such highly technical matters. Therefore, wider notions of input-legitimacy are necessary, in combination with an increased robustness of the knowledge produced and conveyed by different types of stakeholders.

Regarding the second point, the comparison of the three cases shows interesting results. Starting with the first issue studied — the logic of interaction between the agencies and the stakeholders — all three agencies show a relative openness to stakeholders and a relatively good performance in terms of interactions. The second issue studied — the structure of networks — shows mixed results. Whereas in EPO such structures are dense but limited to specific network formations (mainly by professionals), EMeA and EFSA represent wider and more flexible network structures with different types of stakeholders. Lastly, the adaptation of the agencies to the changing socio-economic context seems to have been somewhat difficult for EPO and partly for EFSA, while it looks as if it has been less problematic for EMeA. Arguably, this could be related to the fact that the areas in which EPO and EFSA operate have been under hefty public and social exposure, whereas EMeA operates in a less socially contested area. The adaptability of these agencies has also to do with their organizational dynamics, particularly *vis-à-vis* the external world, and with their respective self-understanding about their role in relation to society and economy.

For the purpose of this article it is necessary to link these findings and discussions about the input legitimacy of independent European agencies to the general questions about the democratic credentials of soft modes of governance in Europe, the main theme of journal this special issue. The

results presented above are of a preliminary nature. Further empirical analysis is needed, particularly in a view to develop a series of theoretically inspired hypotheses that can be tested systematically through a consistent collection of data. Such in-depth research endeavours will be able to generate explicit explanations (among other things) about the democratic dimension of the dynamics within the networks of stakeholders and between these networks and the corresponding independent agency. In spite of the need for further research, for the time being, the current results of this article show that wider forms of input legitimacy (beyond traditional forms of parliamentary control in the traditional understanding of representative democracy) are necessary for the wider societal acceptance and economic performance of these agencies. Increasingly, experts in the politics of agency delegation acknowledge that the embeddedness of the agencies in their wider social and economic context is an important aspect of their performance. The legitimacy of independent agencies resides in a combination of democratic aspects, which include the four yardsticks mentioned in the opening article of this issue — parliamentary control, societal input, transparency and the quality of deliberation. This article has focused on the second of these four aspects, finding that this societal input varies greatly among the three independent agencies studied. Further research needs to collect detailed data and examine each of these four yardsticks one by one, particularly the quality of deliberation, which has important implications for the social and scientific robustness of the knowledge produced by these agencies, and upon which important allocative and political decisions are made.

Notes

1. Regulation 178/2002 EC of 28 January 2002 (OJ L 31/1).
2. See articles: 'Commission says that GMO risk assessments need improving', *EU Food Law Weekly*, Friday 14 April 2006 and 'Environment Ministers criticise EFSA's GMO risk assessments and call for change', *EU Food Law Weekly*, Friday 10 March 2006.
3. See article: 'EFSA to announce new co-operation strategy', *EU Food Law Weekly*, Wednesday 13 September 2006.

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