

Herwig C.H. Hofmann

‘European regulatory Union? The role of agencies and standards’

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I. Introduction

The past decades of evolution of the EU's legal and political framework have considerably influenced the EU's internal market and the evolution of the internal market has equally had considerable influence on the institutional structure of the Union. With diversification of the Union's policies and policy objectives and the deepening of its integration, the Union has moved from an organisation which was initially primarily seen to be engaged in regulatory activity akin to (quasi-) legislative action, towards an organisation increasingly active also in the field of the administrative implementation of Union law.¹

The central phenomenon which will be at the centre of attention in this short look at changes in regulatory structures of the Union is the great diversification and pluralisation of executive bodies on the European level, which has taken place in order to be able to address the requirements of deepening integration in various policy fields. This development is frequently discussed in the context of an important change in the EU's institutional landscape described as 'agencification'. The result is that next to the Commission, and to a lesser degree the Council and the ECB, now a great diversity of 'offices, bodies and agencies' exercise administrative functions in the EU.² These institutional developments have influenced and continue to influence the evolution of the exercise of regulatory powers in the Union. They have transformed the very nature of the Union not least by the way of setting norms and standards for the internal market.

Understanding the regulation of the internal market as well as critically reviewing and developing ideas for future regulatory governance therefore requires an understanding of both the institutional and the procedural diversity of forms of regulatory activity.

II. The EU and the evolution of the regulatory state

The idea of a regulatory Union is a term borrowed from the concept of a 'regulatory state' which became popular in the second half of the twentieth century. Initially, it was used to illustrate the growth of administrative law based approaches to achieve policy goals. The move towards such

¹ With further discussion, see Herwig C.H. Hofmann, Gerard C. Rowe, Alexander Türk, *Administrative Law and Policy of the European Union*, Oxford University Press (Oxford 2011), 3-20.

² See the formulation of Article 263 paragraph 2 TFEU and 41(1) CFR.

forms of action was widespread both in the US as well as in countries in Europe but may have been most pronounced in some Nordic legal systems such as that of Sweden. The turn towards a 'regulatory state' was undertaken by increasing the public role in setting standards for economic, social, environmental and other matters as well as the growth and diversification of the executive branches of power in the post-second world war period. In this context, the idea of regulation, broadly speaking, denotes diverse forms of governmental intervention to steer policy developments and private action.³

The post second-world war project of European integration was based on creating an internal market, focussing not only on a common customs Union but also, and to an ever larger degree, on deconstructing regulatory barriers to the internal market. That, however, was possible not by de-regulation alone. After all, the necessity of regulation in modern society is apparent from the parallel rise of the 'regulatory state' in all western countries alike. The answer was an EU-based 'approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market' (Article 114(1) TFEU). Approximation takes place on the EU level either by coordination of national regulatory policies or their replacement by EU law. In reality, in most policy areas, both approaches have been undertaken in parallel. Additionally, cooperation in implementation of these new EU regulatory approaches has intensified, often through technically specialised agencies.

However, although regulation is sometimes equated with governance by technical expertise only loosely linked to parliamentary majorities, it is far from an apolitical activity. Regulation aims to achieve certain behaviour by market participants. It is undertaken within the EU's constitutional framework by administrative institutions and forms of act, accompanied by a host of co-regulatory and incentive-based approaches. Setting regulatory goals and choosing the means to achieve them is highly political - not only in the general sense that any policy endeavour that can go wrong can become political due to the necessity of accountability tools such as parliamentary oversight over administrative action. Regulation is also highly political in that regulatory choices will have an immediate influence on value choices in society. Examples are numerous, but for illustration it should be sufficient just to mention the balancing of environmental objectives with economic development goals or the balancing of labour protection and participation rights versus free movement of workers and freedom of establishment.

³ David Levi-Faur, Regulation and Regulatory Governance in: David Levi-Faur (ed.) *Handbook on the Politics of Regulation*, Elgar Publishing (Cheltenham 2013), 3-22.

III. Tools and structures of regulation

The broad notion of ‘regulation’ used in the context of the idea of the ‘regulatory state’ is about ‘steering’ behaviour. The specific institutional design and institutional mix and the applicable forms of act used for such steering and creation of an internal market are the key elements of a particular regulatory regime.⁴ Each regulatory regime is characterised by the particular mix of and different combinations of actors, varying procedures and each enjoying very different conditions of legitimacy and conditions of usage. Most modern regulatory regimes⁵ rely, just as the EU increasingly does, on ‘agencification’ i.e. the pluralisation of actors on the level of executive implementation. Agencies generally are policy specific bodies employing expert knowledge to harness the rising role of scientific and economic expertise in market regulation matters. In the EU, much as in its Member States, the increasing diversity has not been an organic, planned process but has arisen in an evolutionary manner according to the needs and possibilities of individual policy areas.⁶ Also, in the EU as in Member States, private expertise has been harnessed for public regulatory purposes by modes of self- and co-regulation as well as by means of references to public or private standards in public legislation.

The concept of a regulatory regime indicates that different policies require different mixes of tools and approaches to ensure effectively that public policy making is translated into real life. As a result, not only in the EU, the regulatory regime is different according to the internal market policy areas. Energy is not covered by the same regulatory regime as banking and securities regulation, and food safety and chemicals regulation are different from specific regimes for product safety. The creation of specific regulatory regimes is about linking relevant actors to regulate and supervise implementation of a policy and establishing incentive-structures. A good example is the independence of the Central Banks in the Union and the European Central Bank’s powers in this context. Although one might remain sceptical about the justification of expertise, fact is that their use may be important in certain contexts. Bruce Ackerman recalls that the ‘construction of new

⁴ Burkard Eberlein, Edgar Grande, ‘Beyond delegation: transnational regulatory regimes and the EU regulatory state’ 12 *Journal of European Public Policy* [2005] 89-112 at 90.

⁵ David Levi-Faur, Regulation and Regulatory Governance in: David Levi-Faur (ed.) *Handbook on the Politics of Regulation*, Elgar Publishing (Cheltenham 2013), 14; For examples see: Russell L. Weaver, Herwig C.H. Hofmann, Cheng-Yi Huang, Steven I. Friedland (eds.), *Developments in Administrative Procedure: A Comparative View from the Administrative Law Discussion Forum*. Carolina Academic Press (Durham 2016).

⁶ Herwig C.H. Hofmann, A. Morini, Constitutional Aspects of the Pluralisation of the EU Executive through ‘Agencification’, 36 *European Law Review* [2012], 419-443, at p. 421.

power centres, in short, requires a host of complex and context sensitive judgments.⁷ The general challenges of the design of regulatory regimes for governing the internal market are guided and, to a certain degree, limited by the strictures of a multi-level legal system with the limitations of the principle of conferral.⁸ In that context, regulation of the EU's single market was 'about modernisation, re-regulation and the re-embedding of the market within a European context once it had been dis-embedded from its national contexts.'⁹

The 'constitutional' basis for Union action regarding the internal market as an 'area without internal frontiers in which the free movement of goods, persons, services and capital is ensured' (Article 26 TEU) is largely circumscribed by Article 114 TFEU.¹⁰ Article 114 TFEU allows for setting both substantive as well as structural provisions. The EU lacking taxing powers to raise funds necessary to engage in distributive policies, is thus predominantly a normative 'regulatory' Union¹¹ as opposed to a '(re) distributive', social Union. Although creating a legal, regulatory framework for a market will invariably have distributive effects, the EU has not been conferred powers to engage in significant distributive policies with the exceptions of matters such as agriculture and structural policies. Regulation in the EU, therefore, takes place more with the tools of setting and applying norms than with a genuine power of raising and distributing funds.

The EU's main legal basis for creating the internal market, Article 114 TFEU, does however not allow for the EU adopting a general regulatory approach to a certain policy. It only allows for regulation of those matters which require an approximation of laws and administrative practices of Member State provisions in order to enable or enhance the functioning of the internal market. Therefore, it is in principle not possible to pursue with acts under Article 114 TFEU any policy objective linked to the single market. The CJEU in *Tobacco advertising I*¹² most prominently clarified these possibilities and limits to creating a regulatory regime. Therein the Court held that a measure promoting positive integration which is based on Article 114 TFEU may not simply reduce or eliminate regulatory differences between the Member States which hamper negative integration. It must, instead, generally contribute in some way or another to the creation or functioning of the

⁷ Bruce Ackerman, Good-bye, Montesquieu in: Susan Rose-Ackerman and Peter Lindseth (eds.) *Comparative Administrative Law*, Elgar Publishing (Cheltenham 2010) 128-133 at 131.

⁸ Articles 5(1) and (2) TEU and Article 13(2) TEU.

⁹ Christian Joerges, Sound science in the European and global market: Karl Polanyi in Geneva, in: Michelle Everson and Ellen Vos (eds.), *Uncertain Risks Regulated*, Routledge Cavendish (Abingdon 2009), 416-425, at 416.

¹⁰ See the contribution by Septhen Weatherill in this volume.

¹¹ Majone has been most instrumental in importing and adapting a term which was made popular in the US post new-deal period to the European context, by comparing the EU to a 'regulatory state'. See: Giandomenico Majone, *Regulating Europe* Routledge (London 1996), 3-59.

¹² Case C-376/98 *Germany v Parliament and Council (Tobacco advertising I)* ECLI:EU:C:2000:544 [2000] ECR I-8423.

internal market.¹³ However, this relatively clear line has been blurred in subsequent case law. For example in *Inuit II* the Court easily accepts the whole-sale prohibition of a pre-existing market due to regulatory differences between Member States and, as the Commission openly argues before the WTO, the wish to comply with the moral concerns of EU citizens concerned about seal hunting.¹⁴ So, although Article 114 TFEU in principle can only be used to remove existing or prevent likely appreciable future obstructions¹⁵ due to disparities between national regulatory approaches where these disparities have a direct and not merely incidental effect on the functioning of the internal market or the conditions of competition therein,¹⁶ within these limits, there is legislative discretion in relation to the method of approximation most appropriate for achieving the desired result.¹⁷

Although this ‘constitutional part’ of the Union’s regulatory framework has been relatively stable since the creation of what is today Article 114 TFEU in the Single European Act of 1987, the regulatory regimes applicable to internal market policies since have considerably evolved. Prior to the introduction of what is now Article 114 TFEU by the SEA, attempts to build an internal market relied much more heavily on means of ‘negative’ integration, a mutual-recognition based approach relying on individual’s Fundamental Freedoms championed by the case law of the Court of Justice especially since the 1970ies seminal cases of reported in every EU law text book such as *Simmmenthal II*, *Dassonville* and *Cassis de Dijon*. Limitations of national law based on Fundamental Freedoms and obligations of mutual recognition were capable of being enforced by the Court in absence of harmonising legislation specifically because they were based on individual rights and did not require legislative action which in those days mostly required hard to achieve unanimity in Council to be adopted.¹⁸

Since the SEA and today’s Article 114 TFEU, it has become possible to shape the internal market increasingly by means of ‘positive’, harmonised rules and implementation. In a way, this might be regarded as a return to the original blueprint of the Treaty of Rome as envisaged by the founders. The implementation of such positive law has spawned the diversification of regulatory bodies on

¹³Case C-376/98 *Germany v Parliament and Council (Tobacco advertising I)* ECLI:EU:C:2000:544 [2000] ECR I-8423, para 58.

¹⁴ Case C-398/13 P *Inuit Tapiriit Kanatami and Others v Commission* ECLI:EU:C:2015:535 of 3 September 2015; WTO DS400, DS401 *European Communities — Measures Prohibiting the Importation and Marketing of Seal Products* Appellate Body report of 18 June 2014.

¹⁵ Case C-301/06 *Ireland v Parliament and Council (Data retention)* ECLI:EU:C:2009:68 [2009] ECR I-593, para 64.

¹⁶ Case C-376/98 *Germany v Parliament and Council (Tobacco advertising I)* ECLI:EU:C:2000:544 [2000] ECR I-8423, paras 84 and 106.

¹⁷ Eg Case C-66/04 *UK v Parliament and Council (Smoke flavorings)* ECLI:EU:C:2005:743 [2005] ECR I-10553, para 43.

¹⁸ See with further references Jukka Snell, *The Internal Market and the Philosophies of Market Integration*, in: Catherine Barnard, Steve Peers (eds.), *European Union Law* (Oxford: Oxford University Press, 2014) 300-324 at pp 307, 308.

the EU level and the procedural forms of close cooperation between European and national bodies. Especially in areas where either a pro-active approach is necessary in order to ensure that an internal market can be established both positive standard setting as well as more general EU based regulatory tools such as competition law, state aid regulation and policy specific regulatory structures are combined. However, such positive legislation has the tendency to create policy specific solutions. Creating more or less ‘ringfenced’ policy-specific regulatory approaches was not only an initial approach to integration by creating specific Treaties for the regulation of coal and steel (by creation of the ECSC) or for atomic energy (by creation of the EURATOM Treaty), it is also a tendency, albeit less pronounced, to be observed in the creation of specific regulatory islands in the area of food safety, chemicals, medicines, banking, insurance and securities regulation, aviation safety, border controls, the regulation of gas and electricity markets and many others more.

Today’s attempts for ‘Better Regulation’¹⁹ in the Union search for ways to attune the Union’s practices to the needs of modern, pluralistic inter-connected societies. This focusses how, in view of the institutions requirements for impact assessments and public inclusion are following from the legal doctrine, Treaties and the General Principles of EU law can be introduced and strengthened in the reality of the regulatory process.

IV. The agencification of EU regulation

One of the most striking features of the development of modern regulatory regimes has been the rise of the independent agency as a regulatory actor. Functionally, EU agencies are decentralised forms of administration that integrate national administrative bodies into their operation by providing structures for cooperation between the supranational and national level and between the national authorities *inter se*.²⁰

In the EU, the central legal basis for the development of the internal market, Article 114 TFEU, today is also the most frequently used legal basis for the creation of EU agencies (sometimes also

¹⁹ See e.g. the European Commission’s Better Regulation Package of 19 May 2015 (http://ec.europa.eu/smart-regulation/better_regulation/key_docs_en.htm) and the EP, Council and Commission 2003 Interinstitutional Agreement on Better Law-Making (Interinstitutional agreement on better law-making, OJ 2003 C 321/1).

²⁰ On the decentralised integration model, see Edoardo Chiti, ‘Decentralisation and Integration into the Community Administrations: A New Perspective on European Agencies’, *ELJ* 10 (2004) 402-38 at 423-31.

called ‘authority’ – e.g. European Banking Authority – or ‘office’ – e.g. the Office for the Harmonisation of the Internal Market) by legislative act of the Union. In fact, the unprecedented pluralisation of the EU executive, is based on the creation of agencies as single market regulators under Article 114 TFEU.²¹ Only few agencies are created directly by a Treaty provision or have a legal basis in the Treaty.²² Since the 1970s, several waves of EU agencies have been created as bodies with separate legal personality from the EU either by Treaty provision or by legislative act. They exercise administrative functions in various areas of EU policies,²³ but do not follow a single organisational model as public bodies under EU law.²⁴ The result is a plurality of legal persons acting alongside and in cooperation with the institutions of the EU.

The CJEU in *ENISA*²⁵ addressed the issue of whether (what is now) Article 114 TFEU can be used as the legal basis for adopting structural ‘measures’ instead of the legislative harmonisation of the rules of the Member States. The structural measure in question was the creation of the European Network and Information Security Agency (‘ENISA’) - an EU agency with its own legal personality and designed to advise Member States on matters related to safety of information networks. Similarly, *Smoke flavourings*²⁶ concerned the use of (what is now) Article 114 TFEU as the legal basis for the empowerment of an EU agency - the European Food Safety Authority – to participate in a procedure provided by law to establish a market authorisation for certain food

²¹ For example, the European Food Safety Authority (EFSA) and the European Network and Information Security Agency (ENISA), [2004] OJ L 77/1 and the Body of European Regulators for Electronic Communications (BEREC), [2009] OJ L 337/1 are based on Art. 114 TFEU (ex Art. 95 EC). Post-Lisbon, the European Supervisory Authorities (ESA) are based on Art. 114 TFEU. See: Regulation 1092/2010, [2010] OJ L 331/1; Regulation (EU) 1093/2010, [2010] OJ L 331/12; Regulation 1094/2010, [2010] OJ L 331/48; Regulation 1095/2010, [2010] OJ L 331/84.

²² These include the European Defence Agency (which is established now in Art. 42, para 3, and 45 TEU but was originally created by the Council Joint Action 2004/551/CFSP, [2004] OJ L 245/17) and the European Police Office (Europol, Art. 88 TFEU). Legislative acts provide for the structural details of these agencies and their procedural provisions. See, in particular: 2004/551/CFSP Council Joint Action 2004/551/CFSP of 12 July 2004 on the establishment of the European Defence Agency, [2004] OJ L 245/17 and Council Act of 26 July 1995 drawing up the Convention based on Art. K.3 of the Treaty on European Union, on the establishment of a European Police Office (Europol Convention), [1995] OJ C 316/1.

²³ Agencies are in this context for example concerned with vocational training and drug abuse, supervision of financial markets and pensions systems, energy networks, information network safety and various risk regulation matters including food, chemicals, medicines, air traffic, marine safety to name just a few. These functions are often less in the scope of rule-making or decision-making but more regarding collection of information for use by EU or Member State institutions. In some matters, like defence, the development of policies has become quite extensively delegated to agencies.

²⁴ Some agencies are also created as public-private partnerships. Examples are the European Institute of Innovation and Technology (EIT), [2008] OJ L 97/1, the various joint undertakings in the area of research such as the fusion energy model ITER, [2007] OJ L 90/58, and the Fusion for Energy agency of the EU to support it. The results are innovative bodies such as those known as joint technology initiatives under the 7th Framework Programme. These are created as joint undertakings under Art. 187 TFEU, for example, besides ITER, SESAR for air traffic management, [2007] OJ L 64/1 as amended, Galileo for satellite navigation, [2008] OJ L 196/1, and the already mentioned EIT. Their *raison d'être* is explicitly to work differently to a normal “public sector” body: though supported by public funds, they should make decisions from the perspective of commercial edge or expertise.

²⁵ Case C-217/04 *UK v Parliament and Council (ENISA)* ECLI:EU:C:2006:279 [2006] ECR I-3771.

²⁶ Case C-66/04 *UK v Parliament and Council (Smoke flavorings)* ECLI:EU:C:2005:743 [2005] ECR I-10553.

additives referred to as smoke flavourings.²⁷ The underlying question was whether, in the absence of general regulatory powers of the Union in the area of the internal market, Article 114 TFEU could allow the legislator to go beyond merely conferring powers for the adoption of measures directed at the Member States. The question was also whether Article 114 TFEU could be used to create multiple-step regulatory procedures involving standards set on the European level by agencies and – ultimately - agency involvement in their enforcement.²⁸

Smoke flavourings and *ENISA* are both important for the EU's legal system as therein the CJEU officially embraces the view and adapts the EU's legal approach to the fact that the EU's multi-level legal system cannot be understood in terms of a two-level model, in which the EU may exclusively legislate and Member States must maintain all implementing powers. Instead both cases are based on a distinctly integrated understanding of regulatory regimes for the EU's internal market. In *Smoke flavourings*, the CJEU held that the Union legislature enjoyed discretion 'as regards the harmonisation technique most appropriate for achieving the desired result'.²⁹ In *ENISA*, the Court held that the objective 'to improve the conditions for the establishment and functioning of the internal market'³⁰ by creating a 'body responsible for contributing to the implementation of a process of harmonisation' where 'the adoption of non-binding supporting and framework measures seems appropriate,' was in conformity with Article 114 TFEU.³¹ In a field of complex and rapidly developing technical circumstances, the creation of an agency providing technical advice facilitated the implementation of EU law, and thereby made a real contribution to the achievement of the internal market.³² Agencification, as 'low-intensity approximation' through

²⁷ Comments in the literature on these two judgements have included worries that they might 'inflare the perennial tensions underlying the division of competence between the Community and the Member States' and have the 'potential to enliven concerns about the magnitude of the Community's competence': K Gutman, Case note on Case C-66/04, *Smoke Flavourings*; Case C-436/03, *SCE*; and Case C-217/04, *ENISA*, (2006/2007) 13 *Columbia Journal of European Law* 147, 182. For further critical reviews of the cases, especially with respect to the principle of conferral see e.g. Astrid Epiney, 'Anmerkung zu C-217/04, (2007) *Neue Verwaltungsrechts Zeitschrift*, 1012.

²⁸ The UK acknowledged that establishing a detailed decision-making procedure with a regulatory committee procedure assisting and supervising the Commission whose decisions are prepared with input from the European Food Safety Agency established a procedure which could result in harmonisation of national law. That, according to the argument, was too far removed to be acceptable under Art 95 EC.

²⁹ Case C-217/04 *UK v Parliament and Council (ENISA)* ECLI:EU:C:2006:279 [2006] ECR I-3771, paras 45 and 46.

³⁰ Case C-217/04 *UK v Parliament and Council (ENISA)* ECLI:EU:C:2006:279 [2006] ECR I-3771, para 42, with reference to *Smoke flavourings*.

³¹ Case C-217/04 *UK v Parliament and Council (ENISA)* ECLI:EU:C:2006:279 [2006] ECR I-3771, paras 44 and 45. The Court explains that '[s]uch is the case in particular where the Community body thus established provides services to national authorities and/or operators which affect the homogenous implementation of harmonising instruments and which are likely to facilitate their application.'

³² Case C-217/04 *UK v Parliament and Council (ENISA)* ECLI:EU:C:2006:279 [2006] ECR I-3771, paras 60–66. It needs to be added that in *ENISA*, the ECJ did not agree with AG Kokott's Opinion. AG Kokott had argued that Art 95 EC was not the correct legal basis for measures which are not closely related to the approximation of national law. In this way, she argued, it was immaterial whether the measure finally adopted 'had less of an effect on national competences than a genuinely approximating measure' (Opinion of AG Kokott (Case C-217/04 *UK v Parliament and Council (ENISA)*) ECLI:EU:C:2006:279 [2006] ECR I-3771) para 39).

providing advice to national bodies that remain free to exercise their discretion and adopt different measures than the ones proposed is, therefore, possible.³³ The agencification of the Union thus is an approach based on bundling specialist knowledge whilst allowing for subsidiarity-friendly administrative cooperation.³⁴

The Court of Justice added another layer to these considerations in *Short selling*.³⁵ The case concerned predominantly the validity of Article 28 of Regulation 236/2012 on short selling and certain aspects of credit default swaps.³⁶ The case, however, also addresses the creation of the European Securities and Markets Authority (ESMA) on the basis of Article 114 TFEU. ESMA is one of the three EU agencies established in 2011 to support the surveillance of key financial actors within an Economic and Monetary Union.³⁷ Article 28 of Regulation 236/2012 vests ESMA with powers to intervene *inter alia* by adopting binding legal acts addressed to individuals, in the event of threats to the orderly functioning or the stability of financial markets or the financial system in the EU. These may contain injunctions to comply with various disclosure requirements and a prohibition against entering into certain types of transactions, namely those commonly known amongst market participants as ‘short selling’.³⁸

The dispute in *short selling* combined the various strands of the ongoing debate about the limits to Union agencification under the internal market legal basis of Article 114 TFEU. *Short selling*, implicitly confirmed, in line with *ENISA* and *Smoke flavourings*, that Article 114 TFEU allows not only for the adoption of measures addressed at Member States but also for the creation of agencies.³⁹ Whether ESMA can be granted the power to adopt individual measures on the basis of Article 28 of the Regulation – and beyond the limits of delegation of implementing powers under Article 291 TFEU - was according to the Court to be assessed against the criteria of ‘whether or not the decisions of the agency concerned either contribute or amount to internal market harmonisation, in the sense this notion is used in EU law.’⁴⁰ The Court also held that a harmonisation measure under Article 114 TFEU could not only allow for the adoption of a general

³³ Case C-217/04 *UK v Parliament and Council (ENISA)* ECLI:EU:C:2006:279 [2006] ECR I-3771, paras 25, 38.

³⁴ HCH Hofmann, ‘Conflicts and Integration: Revisiting *Costa v ENEL* and *Simmenthal II*’ in M Maduro and L Azoulai (eds), *The Past and the Future of EU Law* (Oxford, Hart, 2010), 66.

³⁵ Case C-270/12 *UK v Council and Parliament (Short selling)* ECLI:EU:C:2014:18 of 22 January 2014.

³⁶ Regulation (EU) No 236/2012 of the European Parliament and of the Council of 14 March 2012 on short selling and certain aspects of credit default swaps [2012] OJ L86/1.

³⁷ Regulation (EU) No 1095/2010 of the European Parliament and the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority) [2011] OJ L 331/1.

³⁸ Article 28 (1)(b) and (2)(a) of Regulation (EU) No 236/2012 of the European Parliament and of the Council of 14 March 2012 on short selling and certain aspects of credit default swaps [2012] OJ L86/1.

³⁹ Case C-270/12 *UK v Council and Parliament (Short selling)* ECLI:EU:C:2014:18 of 22 January 2014, paras 78-86; Opinion of AG Jääskinen of 12 September 2013 in Case C-270/12 *UK v Council and Parliament (Short selling)*, paras 32-34.

⁴⁰ Opinion of AG Jääskinen of 12 September 2013 in Case C-270/12 *UK v Council and Parliament (Short selling)*, para 36.

regulatory measure such as establishing standards for national agencies.⁴¹ Action of an EU agency intervening vis-à-vis individuals could still be deemed the approximation of the Member State provisions in the core sense of Article 114 TFEU. The Court referred to the necessity of creating a ‘common regulatory framework’ of the market in short selling and credit default swaps’.⁴² An exceptional and occasional banning of certain specific market activity was in view of the Court consistent with the requirements of Article 114 TFEU.

Short selling demonstrates, that the establishment of the European Supervisory Authorities (ESA)⁴³ in the banking (European Banking Authority),⁴⁴ securities (European Securities and Markets Authority)⁴⁵ and insurance (European Insurance and Occupational Pensions Authority)⁴⁶ further develops the role of the agency rule-making contribution. The three supervisory authorities are called not only to adopt preparatory measures, but draft regulatory and implementing standards. These standards are preparatory measures to be adopted by the Commission under Article 290 and 291 TFEU.⁴⁷ The founding Regulations establish procedural rules which the Commission has to follow when examining the standards: should the Commission decide not to endorse the draft standards, it would have to send them back to the authorities, reasoning the rejection or the amendments. If the authorities refused to amend the standards, or amended them in a way inconsistent with the Commission’s views, the latter may either reject the proposal, or adopt it with amendments, but only after due coordination with the authorities. The Commission’s power of ‘last say’ on the adoption of standards, as designed in the Regulations, is further qualified by the preambles to the latter which, in particular, confine the right of the Commission to amend draft regulatory standards to cases of incompatibility with EU Law, breach of the proportionality principle and of the fundamental principles of the internal market in financial services.⁴⁸ The

⁴¹ Case C-270/12 *UK v Council and Parliament (Short selling)* ECLI:EU:C:2014:18 of 22 January 2014, para 45; Andreas Orator, ‘Die unionsrechtliche Zulässigkeit von Eingriffsbefugnissen der ESMA im Bereich von Leerverkäufen’, (2013) *Europäische Zeitschrift für Wirtschaftsrecht* 852.

⁴² Case C-270/12 *UK v Council and Parliament (Short selling)* ECLI:EU:C:2014:18 of 22 January 2014, para 114.

⁴³ Directive 2010/78/EU in respect of the powers of the European Banking Authority (EBA), European Insurance and Occupational Pensions Authority (EIOPA) and the European Securities and Markets Authority (ESMA), [2010] OJ L331/120.

⁴⁴ EBA Regulation 1093/2010, [2010] OJ L331/12.

⁴⁵ ESMA Regulation 1095/2010, [2010] OJ L331/84.

⁴⁶ EIOPA Regulation 1094/2010, [2010] OJ L331/48.

⁴⁷ See for instance Case T-326/99 *Fern Olivieri v. Commission and European Agency for the Evaluation of Medicinal Products (EMEA)* [2003] ECR-1985, par 49-53.

⁴⁸ See Recital 23 of EBA Regulation 1093/2010, [2010] OJ L331/12, and ESMA Regulation 1095/2010, [2010] OJ L331/84 and Recital 22 of EIOPA Regulation 1094/2010, [2010] OJ L331/48. Recital 24 and 23 respectively, on their part, report the Commission’s intention to rely on the authorities’ standards in view of the adoption of the relevant delegated acts.

addition of such explanation in the preambles will guide the Court of Justice in the interpretation of the limits of the Commission's capacity to amend the draft standards.⁴⁹

The strong link between the specific needs of the regulated areas and the structured powers of the agencies is not only illustrated by the strengthened protection of the authorities' contribution in rule-making, but is also further confirmed by the delegation to the European Supervisory Authorities (ESA) of the power to adopt individual legally binding decisions. Such a conferral appears particularly delicate. Although in principle, the powers at stake are conceived to be exercised towards national supervisory authorities, in certain circumstances the ESA will be in the position to address their decisions directly to market players.⁵⁰ Such decisions entail the exercise of powers akin to the discretion enjoyed by the Commission in areas such as competition and state aid. In these cases the agencies are obliged to carry out the complex economic assessments required in highly regulated areas such as banking, securities and insurances. With short selling, the CJEU confirmed a trend in its case law allowing conferral on EU agencies of discretionary powers. Despite occasional repetitions of the *Meroni* doctrine which denies transfer of legislative discretion, the transfer of broad discretion to agencies is now established case law of the Court.⁵¹

Perhaps one of the most far reaching approaches to the design of agency guidance to Member State agencies is the ECB 'guideline' which sets the general rules within the European System of Central Banks (ESCB) and binds the National Central Banks (NCB). This is an interesting example of standard setting despite the fact that the ECB is not created by legislative act with a legal basis in Article 114 TFEU but is a creation of the Treaty and a detailed statute added to the Treaty as a protocol, hence enjoying the binding force of primary law.

The reason for the proliferation of agencies is not only to be found in the fact that they are instruments of coordinating implementation of the internal market policies by Member States on the European level. Also, the concept was to create specialist centres of information. In a 2002

⁴⁹ In this context, it can be noticed that the fact that the institutions established the three authorities by denominating them generically as European Supervisor Authorities, might entail the intention to constitute and develop a new model for a shaping of agency powers which encompasses a more prominent influence in the rule-making as well as more active decision-making.

⁵⁰ See Art. 17, para 6, Art. 18, para 4 and Art. 19, para 4 of, respectively, EBA Regulation 1093/2010, [2010] OJ L331/12, EIOPA Regulation 1094/2010, [2010] OJ L331/48 and ESMA Regulation 1095/2010, [2010] OJ L331/84.

⁵¹ See the leading case T-187/06 *Schröder v CPVO* [2008] ECR II-3151 upheld on appeal in C-38/09 P *Schröder v CPVO* [2010] ECR I-3209, para 77; C-281/10 P *PepsiCo* [2011] ECR I-10153 ECLI:EU:C:2011:679, para 67; Joined cases C-101, 102/11 P *Neuman and Galdeano*, ECLI:EU:C:2012:641, para 41; C-534/10 P *Brookfield New Zealand v CPVO and Schniga* ECLI:EU:C:2012:813 para 50: "the CPVO must be accorded a broad discretion in carrying out its functions"; T-145/08 *Atlas Transport v OHIM* [2011] ECR II-2073, para 69, 70 discretion of the Board of Appeals of an agency "is a broad discretion" which "must comply with the general principles governing procedural fairness within a Community governed by the rule of law."

communication from the Commission the key reason for the establishment of agencies was seen in the ability to provide scientific assessments based on technical evaluations which ‘are not influenced by political or contingent considerations’,⁵² and help to create ‘Europe-wide epistemic communities whose technical truths transcend intergovernmental politics.’⁵³ Thus, legislative acts establishing agencies often also envisage agency participation in the adoption of detailed technical rules. This is also in compliance with the case-law of the CJEU which, in light of the Commission’s lack of expertise in certain areas, has required the contribution of agencies to the EU regulatory functions under the case law on the general principle of duty of care.⁵⁴ Matters of internal market regulation presenting highly complex scientific issues, such as manufacturing of medicines and food safety; but also to other areas having a complex regulatory substance, like aviation and maritime safety are therefore subject to agencification. The risks of this approach to a coherent regulatory whole and a representative democratic governance system have been well summarised some twenty years ago by Caporaso who observed that “special purpose authorities fragment power, rely heavily upon expertise, and utilize power and knowledge within narrow decision-making contexts that lack transparency and general popular interest. To the extent that the *res publica* of the EU are preoccupied by the details of civil aviation, regulation of pharmaceuticals, and the labelling fo food goods, genuine poular engagement is unlikely to be forthcoming.”⁵⁵

Irrespective of this critique, the role of EU agencies in regulatory law is increasing in various policy areas. Agencies are not only coordinators of composite procedures in which EU and Member States cooperate by means of joint implementation and enforcement of EU law, but they are also increasingly authors of standards to be used in implementation of EU law by Member States. These roles of agencies have developed next to and alongside the more ‘traditional’ approach of regulatory law which consists of references to ‘outside’ standards set by private and semi-private standardisation bodies and scientific expertise.

⁵² Communication from the Commission – The operating framework for the European Regulatory Agencies, COM (2002) 718 final, 5. For an overview on the point, see Damien Geradin and Nicholas Petit, *The Development of Agencies at EU and National Levels: Conceptual Analysis and Proposals for Reform*, Jean Monnet Working Paper 01/2004, p. 5-8.

⁵³ Martin Shapiro, The problems of independent agencies in the United States and the European Union, 4 *Journal of European Public Policy* (1997) 276-91, p. 282.

⁵⁴ See Case T-326/99 *Artegodan and others/Commission* [2002] ECR II-4945, para 198. Though such statement refers to a scientific risk assessment instrumental to the adoption of an individual decision by the Commission rather than to the making of rules of general scope, the issue posed by the Court – the gap of expertise between the Commission and the agency – can be referred to the rule-making carried out by such an institution.

⁵⁵ James A. Caporaso, The European Union and Forms of State: Westphalian, Regulatory or Post-Modern?, 34 *Journal of Common Market Studies* (1996), 29-52, at p. 49.

V. *Standardisation and technical norms*

Standards, as was mentioned above, are not only set by EU agencies as guidance for implementation of EU policies by national agencies but are also imported into EU law from external sources either on the international, the European or the national levels. They are quite central to implementation and are part of the regulatory regime of the internal market.

Having discussed the main EU-internal source of production of standards for implementation of EU law, that is independent agencies, the EU's regulatory regime also relies on 'external' production of standards i.e. standards set by bodies other than EU institutions and agencies. This does not exclude, however, that agencies rely in their regulatory action on such external standards. Examples for this exist in nearly all fields of risk regulation. Where, for example, the European medicines agency considers suggesting the admission of a new medical product, the review of this will take place according to EU legislation and according to the practice of the agency on international scientifically proven best practice.

Multiple policy fields provide for exactly this mechanism for interaction between European agencies, the Commission and international bodies organised in various forms establishing *initially* non-binding standards, which by reference or explicit incorporation by EU agencies into Union policies can become binding.⁵⁶ Examples are found in many areas. In pharmaceuticals, for example, standardisation activities of the 'International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceutical for Human Use' (ICH), a joint regulatory and industry cooperation established in 1990 by the EU, the US and Japan with the support of the World Health Organisation, are readily incorporated into EU law.⁵⁷ In the field of banking regulation, standards established by the so called 'Basel Committee on Banking Supervision' an venue for cooperation of the heads of several central banks and banking supervisory authorities of developed nations and the EU, as well as the 'International Accounting Standards Board' (IASB), the board of the a not-for profit corporation acting as a privately funded standard setter with a membership reported to include business, academic and

⁵⁶ See for an overview e.g. Andreas Follesdal, Rames A. Wessel, Jan Wouters (eds.) *Multilevel Regulation and the EU*, Marinus Nijhoff Publishers (Leiden, Boston 2008).

⁵⁷ See Bärbel Dorbeck-Jung, *Challenges to the Legitimacy of International Regulation: The Case of Pharmaceuticals Standardisation*, in: Andreas Follesdal, Rames A. Wessel, Jan Wouters (eds.) *Multilevel Regulation and the EU*, Marinus Nijhoff Publishers (Leiden, Boston 2008), 51-71 with reference to the ICH Guidance on Good Clinical Practice being incorporated into the EU Clinical Trials Directive (2001/20/EC) and subsequent regulatory practice.

regulatory authorities are highly influential. Accounting standards used in various contexts in EU law.⁵⁸ The Banking crises following the years after 2008 has laid bare the degree to which Basel regulations and the IASB developed International Financial Reporting Standards as well as the International Accounting Standards have entered into the regulatory environment of the EU, to some accounts rather unchecked for the biases in regulation they provide for.⁵⁹ Many other examples have been collected by scholars looking into ‘Global Administrative Law’ matters,⁶⁰ and some common standards are emerging from comparative studies.⁶¹

Standards adopted by private organisations can assume the status of Union legislation by incorporation through direct reference. Private rules can also constitute a means of implementing Union legislation, as in the field of social policy⁶² or in the environmental field,⁶³ as well as in data protection.⁶⁴ Codes of conduct play an increasingly important role in commercial practices,⁶⁵ and professional activities,⁶⁶ as well as in corporate governance.⁶⁷

Beyond this, the procedures for the establishment, withdrawal, or amendment of standards relating to goods have to comply with requirements under international economic law, especially the World Trade Organisation’s (WTO) agreements, generally on product related rules under the

⁵⁸ Regulation (EC) 1606/2002 of the European Parliament and the Council of 19 July 2002 on the application of international accounting standards, OJ 2002 L 243/1, authorises the Commission in Art. 3 to decide in a comitology procedure on the applicability of international accounting standards as defined in Art. 2. On this basis the Commission has adopted Commission Regulation (EC) 1126/2008 of 3 November 2008 adopting certain international accounting standards in accordance with Regulation (EC) 1606/2002 of the European Parliament and the Council, OJ 2008 L 320/1, as amended, which incorporates international accounting standards, by way of direct reference. See also Dagmar Schiek, Private rule-making and European governance – issue of legitimacy, 32 *European Law Review* (2007) 443-66 at 455.

⁵⁹ Bart de Meester, Multilvel Banking Regulation: An Assessment of the Role fo the EC in the Light of Coherence and Democratic Legitimacy, in: in: Andreas Follesdal, Rames A. Wessel, Jan Wouters (eds.) *Multilevel Regulation and the EU*, Marinus Nijhoff Publishers (Leiden, Boston 2008), 101-143.

⁶⁰ See e.g. Sabino Cassese et al., *Global Administrative Law: the Casebook*, 3rd ed., , IRPA-IIIJ (Rome 2012) Available at SSRN: <http://ssrn.com/abstract=2140384>.

⁶¹ See especially, Sabino Cassese, A Global Due Process of Law? In: Gordon Anthony, Jean-Bernard Auby, John Morison, Tom Zwart, *Values in Global Administrative Law*, Hart Publishing (Oxford 2011), 17-60.

⁶² See Art. 153(3) TFEU (amending Art. 137(3) EC by the reference to Art. 155 TFEU), which allows Member States to entrust to management and labour the implementation of social policy directives.

⁶³ See Art. 17(3) of Directive 2002/96/EC of the European Parliament and the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE), OJ 2003 L 37/24, which provides that Member States may transpose certain provisions of the directive ‘by means of agreements between the competent authorities and the economic sectors concerned’.

⁶⁴ See for example in Article 27 of Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 L 281/31 which envisages the drawing up of codes of conduct subject to the approval of a working party.

⁶⁵ Dagmar Schiek, Private rule-making and European governance – issue of legitimacy, 32 *ELRev.* (2007) 443-66 at 458-60 and 461-2.

⁶⁶ Dagmar Schiek, Private rule-making and European governance – issue of legitimacy, 32 *ELRev.* (2007) 443-66 at 462-3.

⁶⁷ Søren Friis Hansen, Codes of Conduct in: Birgitte Egelund Olsen, Karsten Engsig Sørensen (eds.), *Regulation in the EU*, Copenhagen (Thomson, 2006) Chapter 8.

TBT (Agreement on Technical Barriers to Trade) as well as on food and feed related matters under the SPS (Agreement on the Application of Sanitary and Phytosanitary Measures). Under these Agreements, WTO members are bound to use international standards as a basis for their technical regulations, provided that such regulations are necessary and no more trade-restrictive than necessary to fulfil a legitimate objective.⁶⁸

In fact, this goal is achieved through the intense cooperation between national, European, and international standardisation bodies. National bodies are represented on the European level. The international standardisation bodies include bodies such as the International Standardisation Organisation (ISO)⁶⁹ and the International Electrotechnical Commission (IEC).⁷⁰ There are also international, sector-specific organisations such as the Basel Committee on Banking Supervision.⁷¹ The European and international standardisation organisations cooperate closely and, for this purpose, have concluded cooperation agreements such as the Vienna Agreement between ISO and the European Committee for Standardization (CEN),⁷² and the Dresden Agreement between the IEC and the European Committee for Electrical Standardization (CENELEC).⁷³ Generally, standards produced by European standardisation organisations comply with international standards. Interestingly a large proportion of international standards, especially those set by the IEC, are in fact themselves based on European standards. In the cooperation agreements, the European standardisation bodies agree *inter alia* to respond to and take into account comments by non-European members in their own standardisation work. This almost takes on the appearance of an outsourcing of international standardisation to European organisations.

The strength of European standardisation organisations arises from their unique position in regulating the internal market. In the internal market, the field of product specification and product safety in particular is also addressed by an alternative, co-regulatory approach. Possibly the main source of such external standards was introduced into EU law by the so called ‘New Approach’ directives of the 1980ies. Therein, the Union has limited itself to adopting only the ‘essential requirements’ of health and safety regulation as opposed to detailed technical

⁶⁸ WTO members may abstain from using international standards when such standards would be ineffective or inappropriate for the fulfilment of the legitimate local policy objectives pursued.

⁶⁹ www.iso.org (last access 29 December 2015).

⁷⁰ www.iec.ch (last access 29 December 2015).

⁷¹ www.bis.org/bcbs/index.htm (last access 29 December 2015).

⁷² See: <http://www.cencenelec.eu/intcoop/Pages/default.aspx> (last access 29 December 2015).

⁷³ See the IEC-CENELEC Agreement on Common planning of new work and parallel voting, STANDING CENELEC DOCUMENT CLC(PERM)003 of October 1996.

proscriptions with which products must comply in order to benefit from free movement within the EU. Instead of adopting detailed Union legislation, European Standardisation Organisations (ESOs), CEN, CENELEC and ETSI, are charged with establishing specific standards on the basis of such requirements. The task of developing harmonised standards falls to the ESOs,⁷⁴ generally, on the basis of a mandate from the Commission. The ‘New Approach’ Directives have been codified in a common framework for the marketing of products by Decision 768/2008⁷⁵ with which all Union harmonisation legislation ought to comply.⁷⁶ The Decision makes it clear that the incorporation of its provisions cannot be required by law, but constitutes a clear political commitment by the European Parliament and the Council to abide by its provisions in future legislation.⁷⁷ New Approach directives apply to a wide range of products and safety hazards.⁷⁸

Products can be placed on the market or put into service where they comply with the essential requirements, usually set out in an annex to the directives.⁷⁹ Essential requirements cover public interest concerns⁸⁰ and may deal with certain product hazards, focus on the product as such and its performance, or set out the main protection objective.⁸¹ Generally, ‘essential requirements define the results to be attained or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so’.⁸² This avoids having to permanently adapt legislative directives to technical progress, but also leaves a considerable discretion in the hands of the ESOs in the adoption of standards meeting the essential requirements. The function of essential requirements is, therefore, to allow the assessment of conformity with those requirements in the absence of harmonised standards if published in the Official Journal and transposed into national standards.⁸³ The interesting regulatory approach of these private standards is that compliance with the harmonised standards is voluntary. Manufacturers and service providers are free to develop their own technical solutions. Nonetheless, harmonised standards constitute *de facto*

⁷⁴ See Art. 3(2) of Decision 768/2008/EC, OJ 2008 L 218/82.

⁷⁵ Decision 768/2008/EC, OJ 2008 L 218/82.

⁷⁶ The reference provisions can be found in Annex I of Decision 768/2008/EC, OJ 2008 L 218/82.

⁷⁷ See recital 7 of Decision 768/2008/EC, OJ 2008 L 218/82.

⁷⁸ Where product is not covered by specific Community legislation, including ‘New Approach’ directives, or where not all hazards are covered by such legislation, it falls within the scope of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ 2002 L 11/4.

⁷⁹ See Art. 1 of Decision 768/2008/EC, OJ 2008 L 218/82.

⁸⁰ See Art. 3(1) of Decision 768/2008/EC, OJ 2008 L 218/82.

⁸¹ See European Commission: the Guide to the implementation of directives based on the New Approach and the Global Approach, 2000, 4.1.

⁸² European Commission: the Guide to the implementation of directives based on the New Approach and the Global Approach, 2000, 4.1. See also Art. 3(1)(1) of Decision 768/2008/EC, OJ 2008 L 218/82. However, Art. 3(1)(2) of the Decision makes it clear that Community harmonisation legislation may set out detailed specifications, where recourse to essential requirements is not possible or appropriate.

⁸³ See e.g. Art. 5(2) of Directive 98/37/EC of the European Parliament and the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery, OJ 1998 L 207/1.

binding rules since the economic incentive to comply with the standards which ensure marketability of products is very strong. Developing alternative approaches generally is too time and cost-intensive to be attractive. By creating incentives for compliance with standards, standardisation activity plays an important role in the realisation of an internal market for goods and services and may even be regarded to operate as an essential complement of, or even as a substitute for, Union legislation on health and safety of products.⁸⁴ Also, the CJEU has consistently emphasised that the obligation of the Member States to respect the presumption of conformity of products produced in accordance with harmonised standards can be rebutted only through the initiation of the safeguard procedure by the competent national authority.⁸⁵

Even though standards established in this system facilitate the achievement of an internal market through regulation by bodies with both expertise and familiarity with the use of such standards, they may raise concerns about their accountability and their ability — perhaps even more, opportunity — to favour commercial interests in their decision-making practice.⁸⁶ This is important because although European standards require a mandate from the Commission, private standards are not merely technical translations of political mandates by the Commission, but entail a good deal of political judgment.⁸⁷ On the other hand, it might also be noted that the influence of national standardization institutes has grown in tandem with the revaluation of European standards, since only the national bodies have a vote and the right to negotiate in the preparation and adoption of European standards. Stakeholders such as manufacturers, appliers, consumers, certification bodies, science, authorities, and environmental associations are, after all, not directly involved in European standardization. Their avenue for participation is through national standardization organizations in so-called ‘mirror committees’.⁸⁸

⁸⁴ See Michelle P. Egan, *Constructing a European Market* Oxford University Press (Oxford 2001); Harm Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets* Hart (Oxford 2005).

⁸⁵ See Case 815/79 *Cremoni and Vrankovich* [1980] ECR 3583, para. 10; Case C-112/97 *Commission v Italy* [1999] ECR I-1821, para. 39; Case C-100/00 *Commission v Italy* [2001] ECR I-2785, paras. 3 and 7; Case C-6/05 *Medipac-Kazantzidis* [2007] ECR I-4557, paras. 42 and 49. The presumption of conformity also applies in tendering procedures which are subject to Community public procurement rules, see Case C-6/05 *Medipac-Kazantzidis* [2007] ECR I-4557, para. 50; Case C-489/06 *Commission v Greece*, judgment of 19 March 2009, para. 43.

⁸⁶ The EU is of course not alone with its tendency to delegate standardisation to private or semi-private bodies. Such practices have long predated the EU/EC on the national level (see for an overview the introduction on the International Standardisation Organisation’s website www.iso.org accessed 12 November 2009). References to standards set in this way also exist in the realm of international economic law, e.g. in various provisions of the WTO’s SPS and TBT agreements.

⁸⁷ Harm Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets* Hart (Oxford 2005) 256.

⁸⁸ Josef Falke, ‘Standardization by professional organisations’, in Gerd Winter (ed.), *Sources and Categories of European Union Law* Nomos (Baden-Baden 1996) 656.

Private rule-making therefore raises many issues and concerns. Where the Union institutions retreat and leave it to private parties to fill the void, the legitimacy of private actors becomes an issue of public interest. While such a retreat can be justified on the basis of the rationales set out above, the Union has to take responsibility to regulate this type of regulation.⁸⁹ It thus falls to the Union legislator to frame the relationship between the Union interest and the participation of private actors, and to the Commission to supervise this relationship. More specifically, the decision-making process within such bodies has to provide for an adequate representation of the parties concerned and mechanisms in order to ensure a balanced process of bargaining or deliberation.⁹⁰ In addition, private rule-making has to be transparent enough to ensure the adequacy of the decision-making process and to allow the monitoring of its results. Private rule-making has to be judged also against its promise to offer more efficient regulation than the traditional forms of Union legislation. Applying, by analogy, the standards of the EU's limitations of delegation of powers to private parties established by the *Meroni* doctrine might suggest that entrusting such functions to the European standardisation bodies is possible only if the powers received are the result of an express delegation and are of a clearly defined executive nature. Moreover, the exercise of such powers must be subject to strict review and the same obligations which the delegating authority would have had to observe had it adopted the measures itself.

VI. Conclusions

Studying the nature and evolution of the exercise of regulatory powers in the Union adds to the understanding both of the legal framework governing the EU's internal market as well as the regulatory regimes developed in order to do so. A central finding for understanding the EU's regulatory regime of the internal market is an increasing diversification of forms of act and of actors – both within the EU's executive branch of powers as well as with regard to co-opted private and semi-private rule-makers external to the EU. In that context, the Union has increased its regulatory options by – over time – developing from an organisation primarily engaged in setting the legal framework through legislative action into an organisation increasingly active in the field of the administrative implementation of Union law. Far reaching delegation of powers to EU agencies – not only of externally binding single case decision-making but even of rule-making – is possible under the CJEU case law despite the relative silence of the Treaties in this matter. Further,

⁸⁹ Günther Teubner, Substantive and Reflexive Elements in Modern Law, 17 *Law & Society Review* (1983) 239-85 at 275.

⁹⁰ See Dagmar Schiek, Private rule-making and European governance – issue of legitimacy, 32 *ELRev.* (2007) 443-66 at 465, who considers this as prerequisites for 'substantive autonomy'.

delegation of implementing powers for EU policies or for policies conducted in the scope of EU law can also be undertaken by delegation to bodies created under public international law or private law. Standardisation is a central element of this process. Private and semi-private rule-makers organised on various levels face even more serious legitimacy concerns than public activities by national or EU agencies. Potential of regulatory capture is an issue for all the above. Whilst standardisation fulfils important functions in the regulation of the internal market, questions of legitimacy and participation of such activity need to be closely monitored. Procedural rules for all forms of rule-making in the Union would be a necessity in order to ensure the proper infrastructure of EU law.

Overall, the major development is that the Union is moving ever further away from a two-level legal system, with the Union legislating and the Member States implementing and is evolving towards an integrated legal system linking the various levels through ever more procedural cooperation in implementation. The past years have seen a reinforcement of earlier trends towards deeper integration, though not predominantly in the sense of ever more matters being addressed by EU legislation. On the contrary, the use of EU agencies as coordinators of the activities of the Member States in implementing EU policies might even be seen as a means of replacing the need for increasingly detailed legislation at the EU level aiming to harmonize Member State law.