The Politics of Systematization in EU Product Safety Regulation: Market, State, Collectivity, and Integration

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Acknowledgements

This book started as a Ph.D. thesis at the European University Institute in Florence. It has undergone a substantial change since then and will now come to print 2 years after its defence in 2011. The road towards its publication was windy and is, regarding its contents, still not walked to an end. The biggest obstacles on this way have still not been removed: My doubts still remain as to whether my conception of markets and statecraft, regulation and law, coherence and fragmentation, collectivity and individual protection within the EU are correct. Knowing that trying to cope with such broad ideas may create more confusion than answers, I tried to conceptualize my thoughts in the best possible way and think that I cannot do any better at present.

The road started at the Justus-Liebig-University in my hometown Giessen during my studies in Germany under the supervision of *Patrick Gödicke*, *Thilo Marauhn*, and *Jan Schapp*. Working on legal questions regarding pharmaceutical law, I was unsatisfied with the lack of coherency and concepts of legislation at EU level. Still being trained in the traditional continental dogmatic way, such a feeling towards EU law is comprehensible, as German legal education has trained my mind to the systematic analysis of law to an extent at which it was no question for me that law shall always aim at the establishment of a system. I am particularly grateful to my lawyer friends from the Giessen days, *Markus Berliner*, *Franziska Böhm*, *Thorsten Dreimann* and *Til Kappen*, each of whom I owe a lot to.

With that preconception of German legal training in mind I was lucky to be admitted as a fellow to the law school of the University of Wisconsin-Madison. I continued my studies in pharmaceutical law under the supervision of *Alta Charo* and *John Kidwell*. Together with *Heinz Klug*, *Paul Motivans*, *David Trubek*, and *Stewart Macauley*, they pushed my preconceptions of the systematics of law to the limit. They strongly emphasized that I was wrong, trying to convince me that coherency and systematic features may be a facet of law, however, that it is not so important whether a legal system aims towards coherency. They confessed straight away that law was politics, and therefore one may only ask whether it follows the right politics. Being confronted with these for my ears harsh claims from the then newly emerging movement of New Legal Realism, I was unsure whether what I had

learned in Germany was at any use at all. As a result I started to go deeper into the social analysis of law, becoming a critical student of critical legal studies, the sociology of law, and the movement of New Legal Realism. After having produced a LL.M. thesis on pharmaceutical law, which was with any word a reflection of my premature undecided struggle between dogmatism and social analysis, I was admitted to the European University Institute in Florence still with a view on producing a piece to systematize EU pharmaceutical law. Upon a short visit to Luxembourg, *Herwig Hoffmann* has brought my attention to the specifics of the study of risk regulation. With all that in mind, arguments from classical German dogmatic training, arguments from its rejection through Old and New Legal Realism and the newly emerging concept of the study of risk regulation, I started working on the systematization of EU pharmaceutical law. During my discussions, particularly with *Fabrizio Cafaggi*, *Moritz Jesse*, *Christina Koop*, *Dennis-Jonathan Mann*, *Hans-W. Micklitz*, *Norbert Reich*, *Hanna Schebesta*, *Sebastian van de Scheur*, *Heike Schweitzer*, *Dennis Patterson*, *Ernst-Ulrich Petersmann*, *Giovanni Sartor*, *Paul Verbruggen*, *Bart van de Vooren*, *Maria Weimer*, and *Neil Walker*, it became quickly clear that I could not use both the area of pharmaceutical law and systematization without further questioning the concepts behind them. It turned out that I had to broaden my perspective in several regards: My problems with pharmaceutical law were actually problems of product safety regulation, which also embraced products regulated under the "new approach", food law and chemical law. And the problems I had with systematization turned out to be a problem of the general concept of the EU as a state and regulative entity. That was also the point where I threw away most of what I had written so far and started afresh. I understood that I could not grasp both notions of systematization and product safety law without a firm understanding of EU's character as a mixed legal system and its "law in action". I hence spent a trimester as a visiting scholar at the London School of Economics under the supervision of *Julia Black* and conducted several interviews at EFSA and EMA.

At the time of the defence of my thesis, my struggle with all the huge questions of EU law and regulation that had popped up during my studies were still not solved. The constant disagreement of *Hans-W. Micklitz* with my work (which I now believe had more an educational purpose) has already made me change some and clarify and substantiate most of my positions within the thesis. Upon defence I had produced a piece which provided some answers to these questions, however, most still not satisfying. The discussion with the members of my defence committee, *Julia Black*, *Fabrizio Cafaggi*, *Hans-W. Micklitz*, and *Ellen Vos*, was extremely important for this book. Their review of my thesis and the way they disputed my arguments during the defence were most important for the transformation of my thesis into this book.

A subsequent short stay as a post-doctoral researcher at the University of Amsterdam (UvA) further influenced my views of the systematics of law. In this respect, I am particularly grateful to *Deidre Curtin*, *Bram Duivenvoorde*, *Christina Eckes*, *Martijn Hesselink*, *Chantal Mak*, *Joana Mendes*, and *André Nollkaemper* who have supported me at UvA with more enthusiasm than I deserved.

This book would not have been possible without the support of my supervisor at the law faculty of the Ludwig-Maximilians-University in Munich, *Thomas Ackermann*, who not only gives me most academic freedom but also supports my academic endeavours in all possible ways. The Munich Risk and Insurance Center led by *Andreas Richter* has become my new intellectual home, allowing me to deepen my knowledge especially with regards to several interdisciplinary aspects of risk and regulation. My colleagues *Stefan Arnold*, *Timo Fest*, *Max Förster*, *Jens-Uwe Franck*, *Lars Hornuf*, *Stephanie Meyr*, *Daniel Petzold*, *Nikolaos Simantiras*, and *Christoph Weber* deserve special mention as they have become most patient listeners and valuable discussion partners.

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Writing this piece in another language than my native tongue, I need to apologize to those who attach great importance to the enunciation of English in a specific way. I am indebted to *Nicholas Lawrence McGeehan* for the comprehensive and timely review of an earlier version of this piece.

As I received my basic education as a lawyer in Germany, which means in a legal education system where coherence and systematic argument of black letter law still play a major role, if not the only role in law, I am very much aware of my "homeward bias" in legal thought. Because of this fact I need to confess that I succumbed to this bias according to both the overall topic and question of this book and also to a large part to the answers I am presenting. However, I tried to at least take into account and understand other legal thinking throughout the analysis. It may be upon the reader to judge in how far I was able to succeed.

My family and friends deserves gratitude for accepting that I may walk different roads and in a different way than most of the members of my family and my friends do. In this respect special thanks go to my mother *Ingrid*, who never lost the basic direction in difficult times. Thanks also to my brothers who have always been supporting me in different ways. I also need to thank my mother-in-law, who has supported my endeavours right from the start.

Tradition has it that the ones who suffered and yet supported the most are mentioned last. *Kathrin* did not only proof read the first draft, she also took the burden to finance large parts of this adventure and took the massive side effects that academic work comprises with enviable sereneness.

Munich
September 17, 2012

Contents

Abbreviations

AD	Anno Domini
Art.	Article
BGB	Bürgerliches Gesetzbuch
BSE	Bovine spongiforme Enzephalopathie
CE	Communautès Europèennes
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
Chap(s).	Chapter(s)
ChemG	Chemikaliengesetz
CFI	Court of First Instance
CFR	Charta of Fundamental Rights
CLP	Classification, Labelling and Packaging
CLS	Critical Legal Studies
CMPH	Committee for Medicinal Products for Human use
EC	European Community
ECJ/The Court	European Court of Justice/Court of Justice of the European Union
ECHA	European Chemicals Authority
EConventionHR	European Convention on Human Rights
EEA	European Economic Area
EEC	European Economic Community
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMEA	European Medicines Evaluation Agency
ECSC	European Community for Coal and Steel
ETSI	European Telecommunications Standards Institute
EU	European Union
EUROFUND	European Foundation for the Improvement of Living and Working Conditions
GefStoffVO	Gefahrstoffverordnung
hyph.	hyphenate

ICH	International Conferences on Harmonization
km^2	squarekilometer
LL.M.	Magister Legum
min.	minute(s)
No.	Number
OMC	Open method of coordination
PhD	Doctor Philosophae
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
Sect.	Section(s)
TEC	Treaty Establishing the European Community
TEEC	Treaty establishing the European Economic Community
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom of Great Britain and Northern Ireland
USA	United States of America
v.	von
WTO	World Trade Organization

Introduction

1 Approach and Aims

This book addresses the impact of the increasing role of the legal method of systematization in EU law on the example of EU product safety regulation. The notion of systematization thereby describes the collection and rationalization of the law into an internally complete, consistent and decidable complex of general, abstract propositions. Rationalization of the law means the generalization of legal rules, legal thought, and the formation and systematization of legal institutions.[1] It argues that the legal method of systematization that has been developed in a welfare-state context transforms to be increasingly used as a regulative tool for pro-European members of the legal society to functionally integrate the market. It illustrates on the example of EU product safety regulation as a reference area the impact of systematization on EU law. It then draws conclusions from this phenomenon and seeks to redefine the current place and origin of systematization in the EU legal system. The analysis is grounded on a firm understanding of the genesis and rationales of EU law. As the EU's main purpose in this respect is to "establish the internal market" (Art 3 (3) sentence 1 TEU, emphasis added), the analysis is situated in the broader political context of functional European integration.

I will put forward and establish two main arguments. First, in certain sectors such as in EU product safety regulation, the quality of EU law changes from a sector-specific and reactive field of law to an increasingly coherent legal system at European level. Instead of punctual market intervention,[2] it thereby increasingly governs whole market areas, leaving little or no leeway for Member States' legal systems

[1] See Thomas Raiser, 'Max Weber und die Rationalität des Rechts', *Juristenzeitung,* No. 63, 2008, pp. 853 et seqq., at p.854.

[2] See on the problems arising from EU punctual market intervention into member state legal systems W.-H. Roth, 'Transposing "Pointillist" EC Guidelines into Systematic National Codes – Problems and Consequences', *European Review of Private Law*, No. 6, 2002, pp. 761 et seqq.

and their actors.[3] By doing so, it challenges and often fully replaces the respective welfare-based legal systems in the Member States for the benefit of a market-driven EU legal system.

> "(A) deeper commitment to common interpretation of EU rules across the Member States will increase coherence. But though true, it is not cost-free. Even if one is prepared to engage in the quest for 'systematisation' of the EU's legislative acquis, the consequence of success in such a quest is unavoidably that limits are placed on national autonomy in the areas touched – incrementally, as a 'patchwork' – by the EU. A more coherent system at EU level may lead to a less coherent system at national level."[4]

It follows that the current understanding of systematization in EU law as a value-neutral exercise which only aims at the better organization of the EU legal system conceals its regulatory power, much to the disadvantage of the sovereignty of Member State's legal systems and the institutional balance of the EU. "The concept of law as system operates as a regulative institutional ideal of law"[5] and uses that ideal as justification of its legal agents.[6] Second, at European level, this ideal is in development. It reflects the change of the function of Statecraft from nation-states to the age of market-states.[7] Systematization of law has in history been tied to the ideal of the creation and preservation of certain purposes that defined the basis of a State.[8] While the purpose of systematization has been a main feature of the state-making agenda of nation-states, the same technique of systematization in the EU nowadays creates an internal market. The systematizing exercise is therefore not only a materialization of law, as *Max Weber* has demonstrated on the example of the systematization of law in nation-states. In the EU, systematization is in the first sense a tool of economization, which copes with both the aims and values of the EU legal order and the challenges that arise from the accession into the market-state age.

The current concept of systematization is hence too limited in two ways: First, it is too limited when it is compared to the direct and indirect impact of systematization on the legal sphere of individuals, the EU institutions, and the Member States. Second, it is too limited when it is compared with the rights and values the EU

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[3] See to this phenomenon on the example of contract law G. Wagner, 'Mandatory Contract Law: Functions and Principles in Light of the Proposal for a Directive on Consumer Rights', *Erasmus Law Review*, No. 3, 2010, 47, 48 et seqq.; on the example of state liability N. Zingales, 'Member States Liability vs. National Procedural Autonomy: What Rules for Judicial Breach of EU Law', *German Law Journal*, No. 11, 2004, 419 et seqq.

[4] S. Weatherill, 'The 'principles of civil law' as a basis for interpreting the legislative acquis', *European Review of Contract Law*, No. 6, p. 80.

[5] J. Bengoetxea, 'Legal System as a Regulative Ideal', in: Koch/Neumann (eds.), *Praktische Vernunft und Rechtsanwendung*, ARSP-Beiheft 53, 1994, p. 65.

[6] J. Bengoetxea, 'Legal System as a Regulative Ideal', in: Koch/ Neumann (eds.), *Praktische Vernunft und Rechtsanwendung*, ARSP-Beiheft 53, 1994, p. 65.

[7] P. Bobbitt, *The Shield of Achilles: War, Peace and the Course of History*, New York, Knopf, 2002; D. Patterson and A. Afilalo, *The New Global Trading Order: The Evolving State and the Future of Trade*, Cambridge, University Press, 2008.

[8] The term "State" is used herein to refer to the entity that governs law.

legal system is based upon. These rights and values nowadays do not only mirror traditional peacekeeping aims any longer but also cope with the challenges arising from a change of Statecraft in Europe from nation-states to market-states.

According to the first phenomenon, systematization has not been recognized as a regulatory tool. In EU law, it creates a new integration-method, which transforms the design of EU law. The predominance of judge-made law, as we know from the common-law systems switches to the building of principally gapless legal systems by using the civil-law tradition of the majority of the Member States to achieve market-related aims of twenty-first-century statecraft. The result is a changing role of the European judiciary and a likewise gain of regulatory power for systematizing institutions such as the Commission, European agencies, non-governmental organizations, and non-governmental experts groups. Systematization draws not only on the relationship of public legal institutions but also on the way individuals are addressed. Individuals are affected as they need to cope with a new, market-driven EU legal system that follows its own logic and methodology. In systematized European legal areas, the individual becomes unconnected from its role of nation-state citizen to a mere market-citizen as consumer or entrepreneur. Within the market-state systematization agenda, the individual is therefore targeted as a market-citizen who chooses between the different incentives mechanisms provided. Instead of harvesting for patterns of consumer choice, systematization of product regulation creates normative models, which addresses market citizens in a systematized way as a group in order to create an internal market.

According to the second phenomena, systematization requires a new definition and a corresponding new framework in EU law. The current understanding of systematization is still based on the eighteenth and nineteenth-century concept of the creation of a nation-state, which is hierarchically ordered, endowed with all function of government, and protects and distributes the welfare of the individual citizen. The systems developed nowadays at EU level respond to and govern phenomena of the twentieth and twenty-first centuries: The loss of nation-state's regulatory power results in the need to exercise shared sovereignty, and to use incentive structures instead of top-down regulation. The systematized market-related view increasingly addresses the behaviour of individuals in groups rather than the protection of the individual. The individual is targeted as a mere agent of economy, deriving its ethos for being a citizen mainly from its ability to consume. Thereby a new view to enforcement structures and rights protection that correspond to the systematized addressing of individuals is needed. The prevailing doctrine of individual judicial enforcement needs to be increasingly substituted through private enforcement that copes with these changing legal roles of individuals. These phenomena form new challenges to systematization, which are expressed in the way systematization designs the EU as a state and how it needs to be constitutionalized.

EU product safety regulation forms an ideal test case for this thesis as it has emerged in recent years from a sector-specific and reactive field of law to an increasingly coherent and autonomous legal and even codified system at Union level, which follows its own rules and procedures. EU product safety regulation mirrored already very early this increasing impact of market-state-driven systematization, as

this area has served as playing field for the many regulatory designs for various institutions at EU level. Unlike in nation-states in the 1970s, the impact of such systematization has been largely absent from systematization of EU product safety law. This is due to the persistent but erroneous assumption that systematization exercises have no regulatory function.

2 Methods

The approach this book takes is a contextual European law approach. Taking for granted that EU law forms an independent, autonomous legal system with a likewise evolving European legal culture, which cuts across nation-state's borders with a view of erasing them, problems are viewed through the lens of EU law only. The starting point of analysis is hence the wording of the respective European legislative or judicial provisions. As this thesis is based on a contextual understanding, such analysis is not limited to the syntax of positive law. Law is not only geared towards the realisation of individual rights but also "to achieve specific goals in concrete situations."[9] "The object of scientific research is not so much the legal terminological conceptions, but rather the problems in life they aim to solve."[10] In this sense, law is political. In such an area of political or regulative economic law as the EU legal order, formal legal constructions recede behind the politics of the law.[11] "Law is to take responsibility not only as a policeman for a minimalist or formal legal order, but as an entity that must 'constitutionalise the economy'; placing individuals in an economic context where real private autonomy – or private bargaining on an equitable basis – is possible (beyond the veneer of a formally 'equal' granting of individual rights)."[12]

If we take these sentences as general guidance, we see that it is difficult to recognize the features of systematization through the lenses of the traditional legal categories such as the public/private divide. Approaches to the investigation of these regimes therefore need new pathways. As "(t)he 'makers of the law' do not operate in a void",[13] the scope, meanings, societal settings, and regulative goals, in which these provisions are embedded, form a much more fruitful basis for analysis

[9] G. Teubner, 'Juridification: Concepts, Aspects, Limits, Solutions', in: Teubner (ed.), *Juridification of Social Spheres: A Comparative Analysis in the Areas of Labour, Corporate, Antitrust and Social Welfare Law*, Berlin, de Gruyter, 1987, p. 15.

[10] K. Zweigert/H. Kötz, *Einführung in die Rechtsvergleichung*, Tübingen, Mohr Siebeck, 1996, 3rd ed., p. 45, translation by KP.

[11] E. Steindorff, 'Politik des Gesetzes als Auslegungsmaßstab im Wirtschaftsrecht', in: *1. Festschrift für Karl Larenz*, 1973, p. 230 f.

[12] M. Dawson, *New Governance and the Transformation of European Law: Coordinating EU Social Law and Policy*, Cambridge, University Press, 2011, p. 106.

[13] R. van Caenegem, *European Law in the Past and the Future – Unity and Diversity over Two Millenia*, Cambridge, University Press, 2002, p. 89.

("law in action approach"). In this respect, any analysis of EU law cannot be departed from the evolutionary relationship of Statecraft, culture, markets, and the people acting within these frameworks. EU law hence needs evaluation in the context of the interaction of statecraft, markets, and their players.[14] Crucial for the analysis is hence not so much the form, setting, and legal quality of Union action, but the question *who* decides and acts in EU law to what end. This institutional question is much better fit to tell us about the outcomes of the different values and social goals underlying the respective law and therefore even about the law itself.[15] These insights may then help to understand in which way law is used as an intentional "activity of attempting to control, order or influence the behaviour of others."[16]

The main aim of this book is therefore to use the example of EU product safety regulation to highlight the massive regulative impact that the systematization of EU law has on the EU legal system beyond the mere rationalizing character. In order to achieve this challenging goal within the parameters of this study, it is necessary to leave many interesting questions, which are triggered by the systematization of EU law, open or at least only scratch at their surface. For this reason I will not discuss the embedding of European product safety regulation in its larger context of international law, especially WTO law.

3 Structure

Chapter 1 is largely descriptive and embraces only a few normative elements. However, it will set the scene and pave the way for the substantial arguments which are to come. This book interlinks two main fields of study in EU law, which are product safety regulation and systematization. In order to investigate both concepts, Chaps. 1 and 2 will clarify their form and content.

Chapter 1 introduces the development of systematized product safety regulation in EU law. Product safety regulation in EU law has developed from a rather sector specific field of law to an increasingly systematic and abstract concept, which follows its own methodologies that have become typical for EU product safety regulation. We may identify a "new approach" and a "new governance" regime at work in EU product safety regulation, which both developed at a different speed and to a different intensity. However, both concepts developed in two waves and are gradually merging into one coherent system nowadays. The ECJ in its "Dassonville" and "Cassis de Dijon" judgments catalyzed the systematization of the "new approach"-product regime by introducing a new understanding of market harmonization at

[14] In general J. Bell, *French Legal Cultures*, London, Butterworths, 2001, p. 5; C. Callies/P. Zumbansen, *Rough Consensus and Running Code*, Oxford, Hart, 2010, p. 5.

[15] N. Komesar, *Imperfect Alternatives: Choosing Institutions in Law, Economics, and Public Policy* Cigaco, University of Chicago Press, 1997, pp. 4–5.

[16] J. Black, 'Critical Reflections on Regulation', *Australian Journal of Legal Philosophy*, No. 27, 2002, p. 25.

European level. With regard to "new governance"-products, public pressure resulting from experiences with catastrophes triggered the first wave of systematization. On the contrary, scholars, the Commission, and the European Council have triggered the subsequent second wave of systematization in both regimes jointly. Systematization has been a reaction to scientific or political proposals such as the Sutherland-report, the "Lisbon"-agenda as well as the "new governance" and "better regulation" strategy. Hence, while the ECJ played a significant role during the first wave, its complete absence is notable in the second wave.

In Chap. 2, I will describe the concept of systematization in EU law and regulation. It serves two purposes: It first maps what is covered by the term "systematization" according to European legal history. Second, it aims to increase the awareness of systematization in the context of the European idea. I will show that systematization is not an end in itself. Rather, it has as a regulatory tool influence on major questions and developments in the EU.

I will first introduce systematization as a construction of models. Within this concept, the works of *Savigny* on the *Rechtsinstitut* and of *Weber* on the rationalization of law have been particularly influential. Having sketched their works on systematization, I will devote more time to investigating the casuistic element of systematization. I will map the different traditional forms such as collection, codification, commentary, compilation, and consolidation of law and add a more recent form of systematization, which I will term systematization through application. This form has become especially prominent in the area of regulation, where the regulators conduct systematizing of laws and regulation in their everyday case-to-case work.

Subsequently, I will investigate the impact of systematization on the EU legal system. Systematization may have an effect on several accounts: official documentation regularly perceives systematization as a rationalizing tool only, whose aim is to better organize disparate law. However, the impact of systematization is much stronger: By first addressing individuals with normative overarching collective concepts and second, formalizing the interaction between individuals, Member States, and the EU, it influences the construction of Europe as a market state. The concept of systematization hence mutates according to the change of ideals it aims to achieve from nation-state features to market-state features. In the nation-state, these ideals have been coloured with specific welfare-state language, which resulted in the materialization debate of European private law systems in the 1970s. The EU, however, following a market-creation agenda, is based on different ideals than the welfare-economics of nation-states. The conflict between nation-state values and EU values can be overcome by viewing systematization in light of the specific market-related criteria, inspired by the "market state" theory of Philip Bobbitt. Breaking away from traditional welfare-state models and focusing upon the "market state" features developed by Bobbitt enables us to understand the impact of systematization on EU product safety regulation. This mutation materializes on several accounts in EU law: It contributes to identifying the European people as a market society which is mainly formed and addressed by consumers. Instead of addressing individual citizens and their political rights, EU law targets the individuals in a systematized way according to their role they play as an economic group on the

market. The systematization of EU law furthermore has an impact on the institutional balance within the EU. With respect to its constitutionalizing function, systematization is a general prerequisite for the well-functioning of constitutional pluralism in the EU. To this end, the systematization also works towards establishing itself as a method of integration of EU law into the Member State's legal system. It switches the court's task to "harden" law through ad-hoc judgment to systematized decisions taken by many actors of the European legal society. Thereby, it in fact replaces supplements or underpins the "integration through law" concept. This does not mean that this development is desirable. It is, however, one way to make sense of the evolution and development of the EU legal order.

In Chap. 3, I will relate the findings of Chaps. 1 and 2. The two regimes of EU product safety regulation, which I categorize as "new approach" and "new governance" products, demonstrate such an impact of systematization on EU law: "New approach products" are products falling within the "new approach" methodology of the EU, while "new governance" products describe risky products regimes that were systematized separately from the "new approach", namely, chemicals, pharmaceuticals, and foodstuff and feedstuff. Selected cases from these areas are systematically assessed, exemplifying pars pro toto the dimension of the impact of systematization in these areas on the EU as an institution, the role of the ECJ, Member States, and the individual and legal scholarship.

The impact of systematization on the EU as a market state will be first illustrated by the increasing systematizing efforts with regards to incentives regulation in the area of "new approach"-regulation. The introduction of incentives regimes through the "new approach" agenda provides a textbook example of the success of market-state regulation. According to this impact of systematization on constructing the EU as a market state, European product safety administration is becoming increasingly systematized both in respect of procedure and substance. Traditional models of single enforcement have decreased while procedures of direct administration and collective redress have increased. The collection, recasting, and intensification of law have built an administration that does not allow for influences other than European ones. Member States may take part in decision *finding*; however, decisions are *made* and increasingly also *enforced* at European level. With respect to the wider approach of regulation, responsive regulation is slowly introduced to most areas of EU product safety regulation. In this respect, horizontal models are construed which govern the behaviour of agents in a systematized way. The rationalizing value of systematization will be illustrated through the example of the modernization of the "new approach".

Within the "market state" systematization agenda, the individual is targeted as a "market citizen", which contributes to the creation of a normative "market society". Instead of harvesting for patterns of such consumer choice, systematization of EU product regulation creates normative models, which regulates market citizen's choices in order to create an internal market. As there are very detailed rules in Europe about which risks to accept and what measures need to be taken in order to minimize these risks, a normative European market society is identified although such *Verbandseinheit* does not exist at European level. Furthermore, the information

model underlying the respective European legislation discloses a normative model which addresses the individual through a market-oriented lens as a group of confident consumers. Individuals are hence reduced to fit into the normative group-model proposed by the EU legislator. Both examples manifest a potential clash between the normative models acquired by systematization and existing forms of law in action. This clash may be explained by the need of regulators to take political choices in order to cope with the incoherence in demand in society for regulation.[17] I will call for a bottom-up approach of product safety regulation, which is coupled with the need to top-down regulation. In order to govern this clash effectively, market-state EU law needs to increasingly provide collective rights instead of individual rights.

Systematization furthermore has an impact on the constitutionalization of the EU legal order. On the example of several cases from the areas of "new approach" and "new governance"-products, I will show that in such systematized areas, the role of the ECJ is decreasing. While the ECJ played a significant role in the integration-through-law-process in the past, the increasing role of systematization narrows the margin of manoeuvre of the Court with the result that other actors take over the role as "engine" of integration.

The integrative function of the systematization of EU product safety regulation towards Member States will be illustrated by two concepts, which I call "integration through system confrontation" and "integration through system competition". The first concept relates to an integration method, whereby European law establishes a fully featured legal system, which is applicable alongside the national legal system, has substantially the same requirements, and integrates European law into the national system as future changes will be implemented only according to the regulatory logic of the European system. The European system will thus ultimately be applicable in practice and will thereby "confront" national legal systems. I will illustrate this method through the example of the classification and labelling requirements of REACH when contrasted to the German legal system. "Integration through system competition" works by establishing a European legal system apart from national legal systems, which then compete for application. Substantially, the systems diverge but work to the same end. European law will then be integrated, when the European legal system acquires more attention than the national legal systems. Accordingly, national legal systems need to realign themselves with the "better" European system in order to remain attractive. I will illustrate this example by comparing the European centralized procedure for medicinal products with national authorization systems.

Chapter 4 will then locate systematization of EU product safety regulation within the wider concept of Union law. I will test the existing features of systematization of EU product safety regulation against the requirements of EU law. As to the European legal culture, the fragmentation of EU law does not hinder systematization. In fact, continental law in particular has always been fragmented. Such

[17] C. Sunstein, *Free Markets and Social Justice*, Oxford, University Press, 1997, 131.

fragmentation is no obstacle to systematization and moreover it challenges it. As to the European constitution, I will identify several policy objectives that indeed ask for systematization of Union law and especially EU product safety regulation. Art. 13 (1) TEU and especially the precautionary principle, stipulated within the policy area of environmental protection, require systematization.

However, these policy objectives do not directly translate into competences for systematization of EU product safety regulation. According to the principle of conferral (Art. 5 (1, 2) TEU), any "act" of the EU requires a competence. I will show that systematization indeed qualifies as just such an "act". First and foremost, systematization's normative value supports such a view. Additionally, assorted codes in EU law have been based on an additional competence that explicitly allowed for systematization. As the EU therefore requires a special competence in order to systematize at least through legally binding legislation, it still remains to be seen whether systematization through soft law is also in need of a competence. I will challenge the prevailing view that soft law in general does not require any competence. There is evidence from both written primary law and European court decisions that quite the opposite is true. Taking the significant normative value of soft law especially in the area of the systematization of EU product safety regulation into account, it would indeed be fundamentally at odds with the principle of conferral if we denied such a competence requirement.

As systematization hence requires a competence that goes beyond the competences of the underlying legislative acts, I will investigate whether and to what extent such competences exist. The post-Lisbon competence regime also requires a fresh look into possible competences for systematization of EU product safety regulation. As I will show, both competence areas, that of shared competences and the competence to support, coordinate or supplement, allow for systematization in principle. While within the area of shared competence systematization may be used as an integrative tool, which actively harmonizes Member State regulation, the competence area to support, coordinate, or supplement does not cover such a purpose. Systematization is only possible on the condition that it covers only EU law, which supplements Member State legal systems. Following this logic, Art. 114 (1) TFEU read in conjunction with the doctrines of implied or resulting powers may serve as a sound competence norm for the systematization of areas, which are covered by shared competences. Art. 352 TFEU may provide the basis for the systematization of acts of EU product safety law within the area of the competence to support, coordinate, or supplement. The principle of proportionality, however, stipulates certain limits as to the degree to which systematization of EU product safety regulation is possible. Generally speaking, the risk inherent in the generalizing approach of systematization to over- or underinvolve certain safety needs need to be dealt with according to these principles.

The book concludes with identifying the risk to understand systematization of EU product safety regulation as a "mere technical" exercise. It argues for a political understanding of systematization, which is used as a regulative tool to foster market integration. Understanding systematization in this view enables us also to limit its regulatory scope. Tensions arise specifically where systematization at EU level is

used to implement ideals that cannot be explained by market-integration, typically by enforcing welfare-state models that are typical for one Member State at EU level. Within these areas, the book argues, systematization cannot be used to regulate cultural and value pluralism in the EU with the view of achieving an internal market. The systematized market-state view also requires a new understanding of EU law. In areas transferred at European level in a systematized way, the enforcement of EU law follows specific market-state rationales which are different from the nation-state. In order to ensure effective enforcement of this market-state EU law, enforcement structures hence need also adopt these rationales at EU level.