

# Contents

|          |   |           |
|----------|---|-----------|
| <b>1</b> | <b>Mapping the Systematization of EU Product Safety Regulation.....</b>   | <b>1</b>  |
| 1.1      | The Emergence of Conceptual Risk-Based Product Safety Regulation .....  | 2         |
| 1.1.1    | The Different and Yet Common Development of ‘New Governance’- and ‘New Approach’- Products – A Summary .....                | 3         |
| 1.1.2    | The Case of ‘New Approach’-Products: From Experimental Restraint to Systematic Horizontal Concepts.....                     | 6         |
| 1.1.3    | The Case of ‘New Governance’-Products: From Reaction Regulation to Consolidated and Codified Sector Specific Concepts ..... | 24        |
| 1.2      | Conclusion .....  | 43        |
| 1.3      | The System of EU Product Safety Regulation and Its Application.....   | 44        |
| 1.3.1    | Pre-market Regulation .....   | 46        |
| 1.3.2    | Authorisation or Approval .....   | 49        |
| 1.3.3    | Post-market Regulation.....   | 51        |
| 1.4      | Conclusion .....  | 59        |
| <b>2</b> | <b>Mapping Systematization in EU Law .....</b>  | <b>63</b> |
| 2.1      | The Concept of Systematization in the Nation-State and in the EU – A Mutation .....   | 65        |
| 2.1.1    | The Common Heritage of Systematization in Europe.....   | 65        |
| 2.2      | The Limited Transferability of The Nation-State’s Concept of Systematization on The EU.....                                 | 84        |
| 2.2.1    | Systematization in the Nation State – Breaking Feudal Systems to Make Territorially Confined Communities of Destiny .....   | 84        |

|                           |   |     |
|---------------------------|---|-----|
| 2.2.2                     | Systematization in the EU – Making<br>the Internal Market.....  | 90  |
| 2.3                       | Conclusions: Systematization in the EU – A<br>Mutation of Nation-State Systematization.....                       | 104 |
| <b>3</b>                  | <b>Systematization of EU Product Safety Regulation – Governing<br/>the EU Market State .....</b>                  | 107 |
| 3.1                       | The Transformation into the EU Market State<br>on the Example of EU Product Safety Regulation.....                | 108 |
| 3.1.1                     | Loss of Control Over Key Features<br>of the Regulatory Sphere .....   | 111 |
| 3.1.2                     | Relocation of Sovereignty.....  | 112 |
| 3.1.3                     | Balance of Powers.....  | 113 |
| 3.1.4                     | Widening of Choices and Provision of Incentives .....   | 114 |
| 3.1.5                     | The Changing Role of the Individual:<br>From the State-National to the Market-Consumer.....                       | 116 |
| 3.2                       | Systematization of EU Product Safety Regulation<br>as Creation of the EU ‘Market State’ .....                     | 117 |
| 3.2.1                     | Systematization as Market-Administration Building.....  | 117 |
| 3.2.2                     | Systematization as Market-Society Building.....   | 134 |
| 3.2.3                     | Systematization as Constitutionalisation .....  | 143 |
| 3.2.4                     | Systematization as Integration .....  | 152 |
| 3.3                       | Conclusion .....  | 165 |
| <b>4</b>                  | <b>Systematization of EU Product Safety Regulation<br/>and European Primary Law .....</b>                         | 167 |
| 4.1                       | Systematization and European Legal Culture .....  | 167 |
| 4.1.1                     | Diversity.....  | 168 |
| 4.1.2                     | EU Product Safety Law as a Hybrid Multilevel System.....  | 173 |
| 4.1.3                     | EU Product Safety Law as a Mixed Legal System .....   | 174 |
| 4.2                       | Systematization of EU Product Safety Regulation<br>and the European Constitution.....                             | 177 |
| 4.2.1                     | The Policy Objectives of Systematization<br>of EU Product Safety Regulation<br>in the European Constitution ..... | 177 |
| 4.2.2                     | Competence for the Systematization in EU Law .....  | 193 |
| 4.2.3                     | Limits to Systematization of EU<br>Product Safety Regulation .....  | 218 |
| 4.3                       | Conclusions.....  | 222 |
| <b>Epilogue .....</b>     | 225   |     |
| <b>Bibliography .....</b> | 227   |     |
| <b>Index.....</b>         | 251   |     |

# Abbreviations

|               |  |
|---------------|--|
| AD            | Anno Domini  |
| Art.          | Article  |
| BGB           | Bürgerliches Gesetzbuch  |
| BSE           | Bovine spongiforme Enzephalopathie                                       |
| CE            | Communautés Européennes  |
| 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 <sup>2</sup> | 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   |