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The Law and Policy of Harmonisation in Europe's Internal Market

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Foreword

It is a pleasure to welcome this study of the law and policy of harmonisation in Europe's internal market.

The subject of the internal market is of high importance. Despite all the concerns about the single currency, the internal market remains by all accounts an outstanding success. That success has been recognised very recently even in countries, and in political circles, which have not been the most supportive of European integration, notably in the United Kingdom, Norway and Switzerland.

From a legal viewpoint also, the internal market can be seen as a success. A combination of ambitious but largely effective legislative programmes, and a remarkable body of case law of the European Court of Justice, has laid the foundations of the internal market, and has developed it, with extraordinarily positive practical results. The national courts, too, have made a valuable contribution, recognising the effects of EU law and the role of the ECJ in making the internal market a reality.

Many legal questions of engrossing interest are, however, still open. This book provides an expert study of many of them. They include such issues as the different forms of harmonisation and their varying effects on national law – especially the question whether and under what conditions higher national standards may be permissible; the division of legislative competence between the European Union and the Member States; and in particular the coexistence of different regulatory regimes at EU and national level.

Hence a principal focus of this book is Article 114 of the Treaty on the Functioning of the European Union, the successor of the EC Treaty. Article 114, the principal Treaty provision on harmonisation, contains crucial provisions allowing Member States, exceptionally and under carefully defined conditions, to protect certain major interests – not so much *national* interests, but rather interests of general importance such as the protection of the environment and the protection of public health. When can Member States maintain higher standards to protect those interests, by (in effect) derogating from EU law?

The resulting legal complexities are carefully teased out and fully analysed by Dr Maletić in this book. Her clear and illuminating discussion

will be of value to all those interested in the legal aspects of the internal market.

Francis Jacobs
King's College London

Acknowledgments

The evolution of this book commences several years ago. It is the outcome of innumerable restless hours spent across various cities, particularly Novi Sad, Trebinje, Milan, Cambridge, London, and Washington DC, each of which has had an impact on the ultimate attainment of the manuscript. As is ordinarily the case with gradual, peripatetic studies of this nature, it has benefited from the good judgment of many people.

In particular, I would like to express my deepest gratitude to Professor Sir Francis Jacobs, whose works I avidly read as a student and whose infinite kindness has been as inspirational to me as his eminent thinking as a universally distinguished scholar. I would like to thank him dearly for his magnificently refreshing modesty and his wonderful support. I also feel very much indebted to Professor Michael Dougan and Professor Takis Tridimas for a truly enlightening academic discussion, for their treasured words of encouragement and for taking the time to provide immensely helpful feedback on my doctorate, which have been instrumental in my finishing this enterprise. For the successful completion of this project, I could not have had a better Maestro: I am eternally grateful to Professor Andrea Biondi for guiding me along the 'diritta via' with endless knowledge, wisdom and charisma.

Looking back over the years, I realise that this undertaking has flourished as a result of the interminable assistance of the talented people that I have had the good fortune to meet. Special thanks are due to Professor Piet Eeckhout for his relentless enthusiasm and dependable advice. I would like to show my greatest appreciation to Dr Veerle Heyvaert for having faith in my work when it was still in its early stages. I am very grateful to Angus Johnston, who has impressed me as extensively for his academic accomplishments as for his limitless magnanimity. I further need to convey thanks to Mike Meehan and Shirley Whitfield for their profoundly moving trust and confidence. I also want to take this opportunity to thank Dr Alina Tryfonidou for her sincere friendship as a wonderful colleague.

This research would not have materialised without the intellectual curiosity imparted to me while taking my first steps in the study of law. I wish to express my heartfelt gratitude to Professor John Bell for his unconditional benevolence when deciding to embark on my postgraduate

endeavours. I am very grateful to Professor Andrej Savin for introducing me to the intricacies of EU law. I remain forever indebted to Dr John Allison and Professor Richard Fentiman for an academic interview at Queens' College that has determined my professional life: I thank them fondly for all their support during the years spent in Cambridge.

Finally, I must extend my gratitude to the superb Edward Elgar team for their impeccable efficiency, patience and opportunity to publish my literary composition. I hope that those brave enough to choose to venture into reading the pages that follow find the journey through the meanders of this elaborate and often unpredictable legal field as fascinating as I did.

None of the friends and colleagues mentioned throughout bear any responsibility for the views expressed in this book, which are entirely my own.

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Introduction

The creation of the internal market, 'an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured',[1] has long constituted a primary objective and justification for the European integration project. It remains to date a key parameter for the overall success of this legislative endeavour.

One of the most fundamental instruments for the furtherance of European harmonisation is Article 114 of the Treaty on the Functioning of the European Union (TFEU), a legal base enabling the European institutions to adopt measures for the approximation of national provisions that have as their object the establishment and functioning of the internal market. Article 114 TFEU, as the key vehicle for the advancement of 'positive harmonisation', that is, the approximation of national norms through European legislative intervention, represents a vital and forceful complementary tool in the attainment of market integration to 'negative harmonisation', that is, the indirect approximation of national norms resulting from the deregulatory effects on Member State laws of the case law of the European judiciary.[2] Much attention has been devoted to the latter type

[1] Article 26(2) TFEU. Article 26(1) TFEU states: 'The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties.' Reference is made throughout to legal texts and other documents publicly available on the EUR-Lex website: © European Union, http://eur-lex.europa.eu/. Only European Union legislation printed in the paper edition of the *Official Journal of the European Union* is deemed authentic. The Treaty of Lisbon, signed at Lisbon, 13 December 2007, has amended the Treaty on European Union and the Treaty establishing the European Community, (OJ 2007 C 306, p. 1). See, for a table of equivalences setting out the new numbering following the Lisbon reforms, the Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (OJ 2010 C 83, p. 361). Pursuant to Article 1 TEU, the Union replaces and succeeds the European Community. An overview of the modifications introduced by the Lisbon Treaty can be found in the European Parliament resolution of 20 February 2008 on the Treaty of Lisbon (OJ 2009 C 184, p. 25). For a detailed discussion of the amendments made, see M. Dougan, 'The Treaty of Lisbon 2007: Winning minds, not hearts' 45 *Common Market Law Review* (2008), pp. 617–703.

[2] Pursuant to Article 19(1) TEU, the Court of Justice of the European Union

of harmonisation, examining, where legislative effort has been scarce or unsatisfactory and judicial developments flourished, the impact of the judgments of the European Courts on the scope of regulatory national autonomy. Many studies have thus focused on the substantive aspects of European Union law, encompassing the free movement of goods, services, persons and capital, 'in the absence of common rules'.[3] In this context, the potential for Member States to invoke interests such as consumer, health or environmental protection to uphold national norms representing obstacles to the process of European market integration has been amply analysed. However, significantly less emphasis has been placed on delineating the competence of the European institutions to take legislative action and the concomitant, residual power of Member States to continue applying or introduce new precautionary national legislation in the *presence* of such European approximation norms. This book[4] purports to make a contribution in this regard, by providing an extensive exploration of the harmonisation paradigm encapsulated by Article 114 TFEU.

Even though issues like the important question of Union competence enclosed within this fundamental provision have been, especially in the light of the *First Tobacco Advertising Case*,[5] enthusiastically discussed, less emphasis has been placed on uncovering the exact implications of the model of harmonisation currently selected for the purposes of the creation of the internal market. It is the aim of this book to examine the crucial and unusual interplay between the forceful trade integration premise inherent in Article 114(1) TFEU and the contradictory ability of Member States to derogate from harmonisation norms on the basis of related market policies encapsulated by Article 114(4) TFEU et seq., as well as the way the Commission and Courts have responded to it, so as to evaluate the Treaty's proposed solution to the balancing between economic integration and welfare protection within the Union. Deployment of Article 114 TFEU 'generally leads to Community legislation touching the most diverse

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is stated to include the Court of Justice (formerly the Court of Justice of the European Communities), the General Court (formerly the Court of First Instance of the European Communities) and specialised courts (formerly designated 'judicial panels').

[3] See the Case 8/74 *Dassonville* [1974] ECR 837 and Case 120/78 *Cassis de Dijon* [1979] ECR 649 line of jurisprudence.

[4] The book has partly evolved through ideas presented at the Institute of Advanced Legal Studies in London (Hart Legal Workshop), the University of Edinburgh, the University of Lecce, and the Inter-University Centre Dubrovnik. I am extremely grateful to the conference organisers and participants for their helpful observations.

[5] Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8419.

areas of national law'.[6] By scrutinising a notification procedure traditionally meant to comfort national authorities concerned that the level of protection selected as the European standard may not cater for public policy objectives to the same extent or in the same way that the domestic market would, the book examines the potential to accommodate national regulatory differentiation within the European Union's integrationist agenda. Inherent in this provision, which both enables the European legislative institutions to introduce harmonisation norms approximating national laws, and, at the same time, authorises Member States to derogate in prescribed circumstances from the introduced common standards, is the constitutionally imperative compromise between the European Union's legislative competence and residual scope for Member State regulatory autonomy.

The book is structured around the text of a specific Treaty provision, Article 114 TFEU, through the lens of which the European internal market can be examined. The research is divided into five main parts.

Chapter 1 locates the Article 114 TFEU paradigm within the broader context of market integration. In particular, the section provides an overview of the harmonisation process, outlining the complementary rationales for positive and negative integration. Exploring first the scope, success and limitations of negative integration, the section revisits some of the main rulings and underlying principles that have informed the Court of Justice 'in the absence of common rules'. The chapter then proceeds to describe the model of harmonisation envisaged by Article 114 TFEU, offering a historical introduction to this important market-building provision and explaining its functioning against the background of comparable procedures located in other areas of the Treaty. By examining the interaction between positive and negative harmonisation, the section highlights the significance of Article 114 TFEU and ultimately seeks to assess its value as a parallel and as an alternative to negative integration for the completion of the internal market.

Chapter 2 analyses the competence of the Union, depicting the legislative instruments available for the attainment of market integration. The chapter initially sets out the trade promotion premise in Article 114 TFEU, with specific emphasis on paragraph one of Article 114 TFEU. It then explores the extent to which, despite the principle of attribution of powers and the seminal *First Tobacco Advertising Case*,[7] Article 114(1)

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[6] Opinion of Advocate General Jacobs in Case C-350/92 *Spain v Council* [1995] ECR I-1985, para. 26.

[7] *Germany v Parliament and Council*, supra note 5.

TFEU has been adapted to cater for non-trade-related interests. The innovative structure of the discussion, looking in detail at the Treaty text by considering in turn the terminological components of the competence formula and tracing its interpretation in the Court's case law, is intended to contribute to the existing literature whilst defining fully the relevant background for the remainder of the study. The salient aspects of the duty contained in Article 114(3) TFEU for the EU legislature to pursue 'a high level of protection' in proposals based on the first paragraph of Article 114 TFEU are examined, with a view to assessing the breadth of the legislative advancement envisaged therein. More familiar issues such as the conundrum regarding the scope of European competence, the divide between centralised and regional authorities, the principles of proportionality and subsidiarity, the impact of policies influencing economic legislation, are developed in an unexplored context and assume a new dimension in this work. Finally, this section discusses recent regulatory trends under Article 114 TFEU, in particular outlining the implications of a potential shift towards exhaustive harmonisation in an area demanding merely qualified majority voting rather than unanimity in the decision-making process.

Chapter 3, focusing on the remaining provisions within Article 114 TFEU and complementing Chapters 1 and 2 through a detailed account of the possibilities for derogation from European harmonisation norms, investigates the scope for national regulatory differentiation within the context of the internal market legislative paradigm. As the discussion of the notification procedure within Article 114 TFEU constitutes an essential part of the study, the section explores in considerable detail the exact meaning and procedural aspects of the relevant Treaty text. Chapter 3 thus seeks to provide a comprehensive overview of Article 114 TFEU, analysing thoroughly one by one the provisions therein. The section ultimately purports to illustrate the concern for effective regulatory protection evidenced in these paragraphs of Article 114 TFEU and to highlight some of the most controversial aspects of the notification procedure, with a view to uncovering the implicit allocation of regulatory competence between the European institutions and Member States within the market-building process.

Chapter 4 deploys a collection of emerging case law and related Commission decisions to test the overall effectiveness of the Article 114 TFEU notification procedure. In particular, the section examines the way Article 114 TFEU has been interpreted by the Commission and the Courts, with a view to assessing the actual capability of the Article 114 TFEU derogation mechanism to accommodate national regulatory differentiation within the Union's integrationist agenda. Tracing a range of national justifications put forward to uphold obstacles to economic

integration, the study navigates through the controversial waters of risk assessment and risk prevention and related responsibility allocation within the context of complex regulatory norms. Identifying a number of recurring themes and exploring the functioning of the Article 114 TFEU provisions in practice, Chapter 4 aims to determine whether the harmonisation model proposed under this provision is ultimately a viable one.

Based on the investigations carried out in the previous sections, in Chapter 5 conclusions are drawn as to the overall success of the conflicted harmonisation paradigm proposed by Article 114 TFEU. Identifying potential improvements and possible alternatives to the procedure within Article 114 TFEU, the book ultimately seeks to evaluate the current harmonisation archetype selected for the attainment of the establishment and functioning of the internal market. As part of the appraisal, the role and contribution of the Member States and Union institutions entrusted with its administration are assessed. By scrutinising the scope of the key provision for the completion of the internal market and by highlighting the collaborative rather than adversarial value of national deviations from common European regulations, the study not only complements the literature available on negative integration, but also challenges prevailing tenets in this field. Rather than subscribing to the traditional view that national derogations from attained European standards are reflective of a weak integration process, the study stresses instead the opportunities for reflexive learning and risk prevention resulting from diverse European and national regulatory standards.

1 The harmonisation of the internal market

The 'establishment of the common market is intended to remove barriers to intra-Community trade with a view to merging national markets into a single market achieving conditions as close as possible to those of a genuine domestic market'.[1] Harmonisation in this area can take two forms: positive and negative integration. While the former 'introduces certain standards believed to be reasonable across the Community, negative harmonization rules out certain national standards as being excessive', allowing, in their place, trade to flow freely.[2] Negative harmonisation is thus 'naturally biased in favour of trade and leads to deregulation over time'.[3] A vigorous application of the Treaty provisions on free movement as tools of 'negative integration' greatly diminishes the need to rely on 'positive integration' for the completion of the market-building process.[4] Indeed, extending the scope of the free movement rules has a corresponding impact on the harmonisation process: the 'more that national barriers are, first, vulnerable to attack and, secondly, ruled unjustified under the law of free movement, the greater the scope for deregulation and

[1] Case C-41/93 *France v Commission* [1994] ECR I-1829, para. 19.

[2] H. Unberath and A. Johnston, 'The Double-headed approach of the ECJ concerning consumer protection' 44 *Common Market Law Review* (2007), pp. 1237–84, p. 1240.

[3] Ibid.

[4] The complementary roles of positive and negative integration are reflected in the Healthcare Directive, where the need for EU level action arose following a number of Court of Justice rulings (stipulating that 'neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of the freedom to provide services'), whose precedential value is expressly acknowledged throughout the recitals to the directive, which states that it 'aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice' (Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ 2011 L 88, p. 45)).

inter-jurisdictional competition under the framework of "negative law", and the less extensive the need for harmonisation'.[5]

Nevertheless, the deployment of substitutive deregulatory techniques like the principle of mutual recognition, whereby products lawfully manufactured and marketed in one Member State must be capable, subject to any plausible justifications, of being marketed in the host state, does not undermine the need for positive harmonisation. As will be seen in greater detail below, there are limitations to the deregulatory effects of the Court's jurisprudence, so that mutual recognition 'is not always a miracle solution' for ensuring free movement in the internal market: '[h]armonisation or further harmonisation remains without doubt one of the most effective instruments'[6] for the attainment of further integration. Typically, in the case of a national measure restrictive of cross-border trade being held lawful because justifiable on the basis of a recognised public interest, harmonisation is 'the classic Community response'.[7] Thus '[b]y putting in place a single Community rule, the interest which underpinned the national measure is secured, albeit at Community level, while free trade is also facilitated by the uniformity of the rule throughout the territory of the Community'.[8]

1.1. NEGATIVE INTEGRATION

Negative integration is premised on the removal of national barriers to market harmonisation. In the years of legislative stagnation in the internal market arising from the requirement for unanimity in the Council preceding the Single European Act, deregulation was largely the result of EU institutional paralysis, prompting the Court of Justice, 'in the absence of common rules',[9] to engage in a close scrutiny of national measures potentially disruptive to market integration. Case after case, the boundaries of

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[5] S. Weatherill, 'Supply of and demand for internal market regulation: strategies, preferences and interpretation', in N. Nic Shuibhne (ed.) *Regulating the Internal Market* (Edward Elgar Publishing, 2006), pp. 29–60, p. 30.

[6] Commission Second Biennial Report on the Application of the Principle of Mutual Recognition in the Single Market (COM(2002) 419).

[7] S. Weatherill, 'On the depth and breadth of European integration', 17(3) *Oxford Journal of Legal Studies* (1997), pp. 537–50, p. 544.

[8] Ibid.

[9] See the Case 8/74 *Dassonville* [1974] ECR 837 and Case 120/78 *Cassis de Dijon* [1979] ECR 649 line of jurisprudence.

European Law have been pushed forward to allow for the unhindered development of the fundamental freedoms.

While traditionally the Court of Justice has been reluctant to correct national processes and to extend the scope of the Treaty to 'internal situations which have no link with Community law' on the basis that any discrimination suffered 'under the law of that State falls within the scope of that law and must therefore be dealt with within the framework of the internal legal system of that State',[10] the boundaries with national regulatory autonomy drawn in early rulings have been progressively redefined,[11] expanding the reach of the Court's jurisprudence. 'In the absence of common rules', the Court has been able to define the cornerstone of the free movement of goods, now Article 34 TFEU, as targeting '[a]ll trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade'.[12] The principle of mutual recognition in the form embraced by the Court of Justice in the seminal *Cassis de Dijon* case,[13] has proved to be a powerful regulatory tactic for the completion of the internal market. As a result of a similarly broad approach eagerly adopted across the other freedoms,[14] coupled with the constitutionalisation of the internal market, through the seminal judgments of *Van Gend*[15] and *Costa*,[16] establishing the direct effect and supremacy of European law over inconsistent national law, the deregulatory impact of the Court's jurisprudence has been far-reaching and indisputable. The 'Court's expansion of Community law jurisdiction through free movement rules, elevated market integration to the controlling rationale in the new areas of the law covered by the supremacy of Community

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[10] Joined Cases C-64 and 65/96 *Uecker and Jacquet* [1997] ECR I-3171, para. 23.

[11] Case C-448/98 *Guimont* [2000] ECR I-10663; Case C-60/00 *Carpenter* [2002] ECR I-6279; Case C-200/02 *Chen* [2004] ECR I-9925. This area of the law is continually evolving: see e.g. Case C-34/09 *Ruiz Zambrano* (judgment of 8 March 2011); Case C-434/09 *Shirley McCarthy* (judgment of 5 May 2011); C-256/11 *Dereci* (judgment of 15 November 2011).

[12] *Dassonville*, supra note 9, para. 5. Article 34 TFEU provides that '[q]uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States'.

[13] *Cassis de Dijon*, supra note 9, para. 8.

[14] See, for example, Case 33/74 *van Binsbergen* [1974] ECR 1299, Case C-76/90 *Säger* [1991] ECR I-4221 and Case C-384/93 *Alpine Investments* [1995] ECR I-1141 in the context of the free movement of services; Case C-55/94 *Gebhard* [1995] ECR I-4165 on the freedom of establishment; Case C-415/93 *Bosman* [1995] ECR I-4921 in the field of the free movement of workers.

[15] Case 26/62 *Van Gend en Loos* [1963] ECR 1.

[16] Case 6/64 *Costa v ENEL* [1964] ECR 585.

law' resulting in a 'spill-over of Community economic rules, with their own particular internal logic, into all areas of national regulation'.[17]

It is perhaps unsurprising for the Court of Justice to adopt a deregulatory approach and for the majority of cases to be resolved in favour of cross-border trade. After all, market integration at the European level has to meet the challenges posed by a long history of regulatory tradition in the various Member States.[18] The phenomenon of negative integration has however produced a lively debate in the academic literature as to whether the pursuit of this model of harmonisation could risk tilting the balance away from legitimate social protection towards a deregulated free market economy in which standards of, inter alia, consumer and health protection would be depressed.[19]

Arguably, however, the fears of deregulation need not be exaggerated. In reality it is improbable that 'a race to the bottom' in regulatory protection is likely to take place as '[t]here is little evidence that electoral or economic advantage can be gained through such tactics'.[20] Furthermore, closer scrutiny of the jurisprudence 'in the absence of common rules', will reveal that there are limits to the strong deregulatory impetus in the context of the fundamental freedoms: the Court of Justice does not exercise 'remorseless deregulation',[21] but rather concedes a degree of autonomy to the Member States. This is reflected by the much discussed *Keck* judgment, which, establishing that national provisions restricting or prohibiting certain selling arrangements are not such as to hinder directly or indirectly, actually or potentially, trade between Member States within

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17 M. P. Maduro, *We the Court* (Hart Publishing, 1998).

18 See for an interesting discussion, S. Weatherill, 'Pre-emption, harmonisation and the distribution of competence to regulate the internal market' in C. Barnard and J. Scott (eds) *The Law of the Single European Market Unpacking the Premises* (Hart Publishing, 2002), pp. 41–73.

19 It has been argued that the internal market 'is to be seen as a truly integrated area where the prevailing conditions are as close as possible to those of a single internal market' (Opinion of Advocate General Tesauro in Case C-300/89 *Commission v Council* [1991] ECR I-02867, para. 10). In the Opinion to Case C-442/02 *CaixaBank* [2004] ECR 1-8961, para. 63, Advocate General Tizzano warned, however, about 'bending the Treaty to a purpose for which it was not intended: that is to say, not in order to create an internal market in which conditions are similar to those of a single market and where operators can move freely, but in order to establish a market without rules. Or rather, a market in which rules are prohibited as a matter of principle, except for those necessary and proportionate to meeting imperative requirements in the public interest'.

20 Weatherill, supra note 18.

21 Weatherill, supra note 7.