

# Fundamentals Of Eu Regulatory Affairs sixth Edition 2012

Fundamentals of EU Regulatory Affairs, 9th Edition  
Regulation Through Agencies in the EU  
EU Regulatory Decision Making and the Role of the United States  
Limits to EU Powers  
Regulatory Delegation in the European Union  
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Rift-lines within European regulatory framework for Biosimilars when taking heterogeneity and variation during lifecycle of the reference biologic and the biosimilar into account  
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Regulation in the EU  
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the past decade has witnessed a proliferation of regulatory agencies at both the national and the eu level this coherent and clearly structured book is the first of its kind to analyse in equal measure and interdependently both national regulatory authorities and european agencies it brings together a select group of highly esteemed contributors authorities in their fields to provide a systematic and over arching view of regulation in the eu unlike many of the previous attempts to shed light on this increasingly opaque and complex co existence of regulatory systems this book takes a genuinely multi disciplinary approach with integrated perspectives from law politics and economics

oliver ziegler raises the question of what role economic interests of the united states play in the regulatory decision making process of the european union critics often assume that u s dominance in the world economy fueled by a powerful business elite has significantly affected eu regulations at the expense of environmental and consumer protection standards the author falsifies this proposition he shows first that the eu often adopts regulations against the explicit opposition of the u s thereby ignoring the principles of transatlantic regulatory cooperation second he demonstrates that business interests in the eu are usually not homogenous and often come second to environmental and consumer concerns in addition the author shows the increasing role of the european parliament in eu regulatory decision making

praise for the book essential reading for anyone interested in the existence and exercise of eu powers in the field of criminal law Öberg s critical examination of the constitutional constraints to eu action also raises many questions that are of great interest in other areas of eu competence the book deserves a wide readership among scholars interested in the constitutional workings of the european union samuli miettinen university of helsinki tallinn university the main strength of this book lies in its comprehensiveness of dealing with the topical issue of eu regulatory criminal law from the fascinating perspective of limits to eu powers its particular contribution to existing scholarship in the field of eu criminal law concerns its focus on judicial checks on the exercise of competences as to which the book offers a convincing proposal for a stricter standard for judicial review in matters of regulatory criminal law and beyond

professor jannemieke ouwerkerk leiden law school an excellent read on competence allocation in eu law and what it means in criminal law context this book guides the reader through very complex questions of the contours of subsidiarity national competences and the exact limits of eu powers it also supplies up to date case studies of financial crimes and the need for the eu to act effectively and thereby increase confidence in the market and the challenges it may cause for national systems a very timely contribution ester herlin karnell vu university amsterdam pursuant to the precepts of eu law eu policy makers are bound to ensure that any eu legislation must fall within the remit of the eu s competences this monograph looks at this highly contested issue with particular reference to european union criminal law it looks at the powers enjoyed by the eu to impose criminal sanctions to suggest mechanisms by which legislative powers could be kept in check the book argues that the main responsibility for providing checks against the exercise of eu power lies with the eu judiciary it argues that the most effective form of review is procedural and through the case study of sanctions provides the basis for such a review innovative engaging and rigorous this is an important publication both in the field of european criminal and constitutional law

this book addresses the regulatory capacity of the eu as it responds to the huge challenge of realizing the single market it explores its weaknesses the eu regulatory networks expert committees and eu agencies formed in response and the exceptionally large and complex transnational regulatory system which has resulted it defines the eu regulatory space as a multi faceted phenomenon of institutional expansion whose shape varies across sectors and changes over time empirically based on the exploration of how regulatory delegation has emerged and evolved in three key eu policies food safety electricity and telecommunications the book disentangles and links together the functional institutional and power distributional factors and their interplay over time into a unified explanation of the many faces of the eu regulatory space

this book examines regulatory capacity beyond the nation state it suggests that we can only understand why eu agencies are able to build eu regulatory capacity if we acknowledge that national regulators provide their expertise staff and resources to the regulatory processes taking place in these eu bodies this raises the puzzle of why national regulators are willing to provide life support to potentially rival organisations the book is devoted to answering this question in order to understand how eu regulatory capacity is created in the absence of a full supranational regulatory bureaucracy to do so the book studies to what extent national regulators from two countries the uk and germany

support eu agencies in their work across four policy sectors drug safety food safety maritime safety and banking supervision the book makes a significant contribution by developing a bureaucratic politics perspective that highlights the importance of national regulators for eu regulatory capacity building

the past years have seen numerous crises from the 2007 2008 financial crisis to the migration crisis and the covid 19 pandemic these crises have significantly impacted eu policy in numerous areas including the economic and monetary union financial regulation and supervision health policy state aid control energy policy migration policy and foreign and defence policy as a result of these crises eu rule making has developed in various ways some developments have had an institutional dimension in that they concerned the actors involved in rule making as exemplified in the introduction of instruction rights of eu bodies vis à vis national authorities or the introduction of reverse qualified majority voting in the council but they also concerned the shape or nature of rules where we have seen the increasing use of regulations as opposed to directives and of soft law instead of legally binding rules the substance of existing rules was also reconsidered resulting for instance in the deviation in practice from the dublin system as regards the distribution of refugees in the eu indebteding itself on a considerable scale in the wake of the pandemic and in the boosting of foreign and defence policies as a result of the war in ukraine eu regulatory responses to crises examines and compares these developments from a legal and a political science perspective it analyses the measures taken successful or not to save banks to ensure a fair distribution of migrants across eu member states or to support the acquisition of vaccines for example this book draws a comprehensive picture of the eu s regulatory toolkit in times of crisis and its enrichment and refinement in reaction to new challenges

european regulatory agencies eras have become increasingly important features in eu decision making they aim to provide expert advice independent of political or economic considerations this book explains whether and under what conditions eras comply with this scientific mandate expanding on rational institutionalism ossege provides novel insights into the behaviour of eras their autonomy from undue external influence and their impact on eu policy making the empirical comparison of three major eras the european medicines agency the european food safety authority and the european chemicals agency not only shows that agencies capitalise on their expertise and rule making competences to protect their autonomy rather in making strategic use of their expertise the eras also guard their autonomy in areas of high political salience though their policy influence in these areas is partially circumscribed

based on these insights european regulatory agencies in eu decision making locates its subject in the wider system of european governance and considers the perennial question of how to reconcile the need for expert advice with democratic decision making

significantly revised and expanded this important book addresses the key pieces of eu legislation in the field of e commerce including on consumer rights copyright electronic identification open internet access electronic payments competition law and digital content

the study based on the principles of genre analysis speech act theory applied to legal discourse and thick description of legal texts was carried out on a corpus of ninety eu regulations on subjects e g customs union competition rules that fall under the exclusive competence of the european union according to the principle of conferral the findings shed light on a new approach to hybridity in eu secondary legislation eu regulations which are hybrid legal texts are inevitably influenced by the legal framework from which they originate and by the political and historical reasons that led the founding fathers of the former european community to address the problem of the so called democratic deficit also from a textual point of view and not only by means of economic and political strategies the textual peculiarity of eu regulation is particularly significant when combined with the contractual nature of eu law thus the results of this study support the hypothesis according to which eu regulations are an instrument created to regulate social behaviour and to address the phenomenon of the democratic deficit from a textual perspective

better regulation in the eu is a perennial and topical question which has important implications for the future direction of eu law while actions directed at improving the quality and accessibility of eu regulation are not novel in recent years the better regulation agenda has significantly affected the structural organisation and day to day operation of the eu legislative process yet many questions about the future of the agenda remain not least in light of brexit exploring the better regulation agenda and its relation to the overall eu legal and political order necessitates an integrated interdisciplinary approach this edited volume presents insights from economics political science and legal scholarship furthermore to allow full understanding it examines institutional practice where the agenda is made and shaped on a daily basis hence the book features contributions from the perspective of the work of the main eu institutions the european commission the parliament the council and the court of justice this results in a seminal

overview of the subject of interest to scholars and practitioners alike

this is the sixth report from the european union committee of the 2009 10 session and looks at the eu s regulation on succession hlp 75 isbn 9780108459757 in october 2009 the eu commission proposed legislation which aims to simplify the law affecting those who die having exercised their right to free movement either by moving to another member state to live or by buying property in a member state other than their own the law of succession regulates how a person s property is dealt with on their death including the mechanism for paying taxes and other creditors establishing who is entitled to inherit the deceased s property and how that property is to be transferred to those entitled to it where this involves the law of more than one member state complications arise which can have a significant impact since the people affected are likely to be emotionally vulnerable because of bereavement the committee states it welcomes the fact that the commission has not proposed harmonisation of the substantive law of succession and support the commission s underlying and more limited objective of prescribing which state s law of succession is to apply to the whole of a deceased person s estate but only to the extent of determining who is entitled to inherit what property the committee believes to go further puts at risk important interests not least property rights the collection of taxes and the protection of creditors the committee also identifies a serious defect in the eu s proposal that it could result in gifts made in the uk by deceased persons during their lifetime including gifts to charity being claimed back by their heirs under a process known as clawback

during the 1980s the stagnation of the internal market the national deregulatory tendencies and the criticism of both the quantity and quality of the body of european legislation constituted a catalyst for the ec to reconsider its legislative tasks taking the white paper for the internal market of 1985 and the single european act of 1986 as its starting point further reflections on the existing body of european legislation and new legislation to be adopted as well as the burden it imposes on national authorities and companies have led to deregulatory and self regulatory efforts also at the ec level these efforts have comprised a greater use of alternative regulatory instruments i e adopting non binding instruments instead of traditional legislative acts on the one hand the flexible nature of the new methods of european governance such as self regulation co regulation open method of co ordination or soft law allows reacting more rapidly to continuing developments on the eu level on the other hand however they lack features such as obligation uniformity justifiability sanctions and or enforcement and as soft law mechanisms are frequently contrasted

with hard law as genuine instruments of european integration over the years the european parliament has faced an excessive use of soft law instruments from the european commission while these instruments have a certain normative nature they are not adopted through a standard legislative procedure the paradox is that while such a quasi legislative process also fulfils the objectives of harmonising national policies it lacks the democratic control characteristic for legislative procedures in the end it undermines the powers and procedures of the european parliament as a european co legislator as a result the value and juridical consequences of this kind of instruments becomes a great source of uncertainty this issue is likely to open a new field of reflection in the context of the better law making strategy in the light of these considerations this background note analyses the institutional and legal implications of the use of soft law instruments on the eu level it begins with introducing the concept of soft law in eu law the discussion then follows with defining various categories of community soft law that have been developed by community institutions further it elaborates on the competence of community institutions to adopt soft law acts after examining the nature and the role of community soft law the discussion turns to the issue of simplification and improvement of eu regulation the background note ends with summoning the role and relevance of soft law with regard to achieving better regulation and good governance in the eu it also concludes on the urgent necessity to increase the implication of the parliament in the elaboration process of soft law

efforts to tackle the trade impeding effects of divergent standards and regulations are at the core of european economic relations this volume draws on literature from several disciplines to develop a comprehensive account of the regulatory strategies and institutional arrangements adopted by the eu in promoting the single market in goods it provides a historical overview and detailed cases studies of the various policy initiatives that have altered the boundaries between the public and private sector in fostering market integration tackling interstate barriers to trade has relied heavily on european law to shape the framework of relations between states and trade liberalization has been facilitated by legal rulings resolving territorial conflicts over regulatory jurisdiction and authority the european court of justice has actively shaped markets acting as a free trade umpire in balancing the goals of market liberalization and market regulation while fostering market compliance although markets are absolutely dependent on public authority the institutional innovation of the eu has been to use the private sector in an ancillary role to the state by delegating responsibility to set standards for market access the eu has chosen to draw on the resources of private actors resulting in a system of governance that is a distinctive hybrid model of regulation composed of state

and non state actors though the outsourcing of public sector regulatory activity was expected to be more effective than the process of regulatory harmonization progress has been difficult the current deficit in setting standards for european wide market access raises concerns about the efficiency and effectiveness of such a regulatory regime egan provides a detailed evaluation of that process highlighting regulatory gaps in the single market and the need to focus not only on the process of market integration but also its outcome and impact on european business comparisons with american efforts to create a national market are made throughout to demonstrate the difficulties of constructing and maintaining a single market american and european efforts to devise a uniform market for commerce and trade have involved both public and private authorities though with different degrees of coordination and centralization as many of the strategies undertaken by the eu echo earlier american market building efforts

the european union and its member states are investing in ambitious programmes for better regulation and targets of regulatory quality this book available in paperback for the first time lifts the veil of excessively optimistic propositions covering the whole better regulation agenda it provides an innovative conceptual framework to handle the political complexity of regulatory governance it approaches better regulation as an emerging public policy with its own political context actors problems rules of interaction instruments activities and impacts focusing on the key tools of impact assessment consultation simplification and access to legislation the authors provide fresh empirical evidence on the progress made in the member states and in brussels drawing on an extensive research project and an original survey of directors of better regulation programmes in europe radaelli and de francesco show how indicators define measure and appraise better regulation policy linking measures to policy processes in which the stakeholders learn by monitoring although better regulation is a top priority for competitiveness in europe and the legitimacy of eu policy the level of commitment and the development of tools vary considerably the major challenge for better regulation is institutionalisation this calls for clear choices in terms of what the eu wants from better regulation essential reading for academics political scientists lawyers and public economists and policy makers in charge of regulatory reforms in governments and international organisations

the european union is often depicted as a dominant global regulator the purpose of this volume is to move beyond establishing that the eu influences global regulation to being to identify under what conditions it exerts that influence toward that end it focuses on the eu s active efforts both bilateral and multilateral to shape regulations beyond its



borders the empirical chapters in this volume are explicitly comparative among foreign partners across international contexts over time and across issues the more conceptual contributions posit an explanation for the eu's choice of regulatory cooperation strategy and take stock of market power europe as a dynamic conceptual framework for understanding and researching the eu as a power collectively this volume advances three arguments the utility of the eu's regulatory power resources is context specific debates about what kind of power the eu is at least as currently conceived are unproductive and that the eu's engagement in the world is better explained through general theories of international political economy this book was published as a special issue of the journal of european public policy

master's thesis from the year 2013 in the subject medicine pharmacology pharmacy grade 1 st class hons dublin institute of technology chemistry course pharmaceutical quality assurance regulatory affairs language english abstract during the course of this thesis evidence was presented and discussed related to the research questions the fundamental question related to the heterogeneity and variation through the life cycle of the biosimilar and the reference biologic remains neglected based on the results collected during this thesis by the stakeholders mainly because those issues were not addressed in any official regulatory guidance document as clear guidance from the ema is lacking with the only available guidance being that once a marketing authorization is issued it is accepted that the quality profiles of the reference biologic and the biosimilar will have different quality profiles abstract within the biosimilar development context there are unaddressed questions by the european medicines agency ema with regard to the impacts of shifts of the quality profile purity and impurity levels of the reference biologic for the biosimilar development program this dynamic is an open issue has potentially implications on the comparability exercise of the before mentioned opinions from experts involved in the guidance drafting process of ema and others were evaluated with regard to the issue

recoge 1 regulatory framework for services and networks 2 procedural rules 3 regulatory framework for terminal equipment 4 frequency policy 5 data protection 6 policy background

regulation in the eu provides analysis of some of the core legal aspects of eu regulation the book focuses on the use of new instruments and methods as alternatives or supplements to traditional forms of legislation such as directives and regulations it also provides an analysis of the use of alternative procedures for creating legislation in the eu and

the use of impact assessment in the adoption of eu regulation the book includes an analysis of the reform of legal instruments proposed in the constitutional treaty this book will be of interest to scholars students and practitioners seeking to understand the core legal aspects of eu regulation and indications of where eu regulation is moving in the future the book is the result of cooperation between legal experts from the aarhus school of business the university of aarhus the royal agricultural university the university of southern denmark and the danish ministry of foreign affairs the book is edited by birgitte egelund olsen and karsten engsig sorensen who are both professors at the aarhus school of business

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