Chapter 1
Introduction

1.1 Introduction to the Problem

> In an internal market of 32 participating countries that are subject to constant scientific and technological progress, important differences in interpreting and applying the rules have emerged, thus undermining the legislation's main objectives – the safety of devices and their free circulation in the internal market. Moreover, there are regulatory gaps or uncertainties with regard to certain products. The regulatory system has also suffered from a lack of transparency and shortcomings in its implementation, in particular in the fields of market surveillance, vigilance and functioning of notified bodies.[1]

This preceding quote was made in the context of a proposal for amending the current legislative framework that regulates the market authorization of medical devices in Europe. It highlights the problems of having multiple administrative levels which may not be operating within a well laid out chain of command that is characteristic of national legal orders. It is a good illustration of how national legal orders are no longer self-contained, clearly demarcated hierarchical systems of legal rules that operate within well-defined national boundaries but are increasingly enmeshed within regional, international and global legal regimes. Simply put, legal rules are generated at multiple administrative levels—and multilevel regulation[2] seems to have become the norm rather than the exception in the world today.

The idea of national legal orders operating within sovereign nation states sustained the foundational division between monistic and dualistic systems of

[1] See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions, 26 September 2012, Doc. Ref. COM (2012) 540 final.

[2] The term was first discussed by way of descriptive examples from the legal arena in Wessel and Wouters (2008), pp. 9–47. This is a critical theoretical concept that has been developed by me in Chap. 2.

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laws.[3] Globalization has undermined the autonomy of such national legal orders.[4] The nature and scope of these changes can be categorized as horizontal and vertical—which by no means are separate and each, seem to feed off the other.

Horizontally, the prime development has been the growing participation of private actors in the development of public legal rules.[5] In some senses the participation of private actors was present earlier—however they operated within the well-defined formats of delegation and accountability mechanisms.[6] The last few decades have seen an exponential growth in the role and function of private actors—viz. private standardization bodies (e.g. ISO, IEC, FSC and ITU[7]); epistemic communities,[8] professional associations, international organizations[9] and non-governmental organizations in rule-making, rule-application and rule-adjudication activities[10] with reference to public rules. A large variety and a great number of private actors are directly involved in these activities—which were previously the exclusive domain of public actors.[11] Public actors increasingly cooperate, compete and in some cases share regulatory authority[12] with a range of private actors specifically in areas of rule-making and rule-application activities.[13] The incentive for participation of private actors in such activities is fairly obvious, in terms of benefitting from the play of rules. What explains the increasing reliance of public officials on these private actors? These public officials are increasingly confronted by technical expertise deficits. These deficits are prone to arise especially in areas of technology regulation wherein rulemaking requires

[3] See for instance for an excellent discussion of Carl Schmitt idea's on this subject, Zarmanian (2006), pp. 41–67.

[4] Ulrich (2010), pp. 1–49.

[5] Chesterman and Fisher (2009).

[6] Aman (2002), pp. 1687–1716.

[7] Although the ITU is an intergovernmental body—it has extensive participation of private experts.

[8] See Haas (1992), pp. 1–35; and Jansen and Roquas (2002).

[9] Here I refer to regulatory activities that go beyond that which is clearly delegated by the member states of the international organizations; and which include soft law that international organizations are increasingly developing in their specific fields of operation. See for instance, Barnett and Finnemore (2004). By one account, the number of international organizations has risen from 37 in 1909 to approximately 1,536 in 2011. Jeffrey (2012), pp. 99–127.

[10] I use these three phases to refer to the activities concerning the formation of these public rules; application of these public rules by public officials and adjudication in the case of conflict between differing interpretations as to the meaning of these public rules. Taken together they constitute the life-cycle of regulations. See for similar usage; Zaring (2008), pp. 563–611 and Camacho-Romisher (2000), pp. 569–601.

[11] Marie Diller (2011), pp. 481–536.

[12] Dezaley (1996) at 84.

[13] See amongst others; Slawotsky (2012), pp. 79–90; Hollis (2002), pp. 235–255; and Meidinger (2006), pp. 47–87.

technical standards that require specific domain knowledge[14] that may not be readily available within generalized public bureaucracies and amongst regulators.[15]

Developments vertically allude to the structure of the rule-making, rule application and rule adjudication activities that have transformed from predominantly hierarchical to decentralized modes of governance. This trend is aligned to the growing involvement of technical experts and is in fact a function of their involvement. Let me explain. National legal orders are structured to operate in a top down hierarchical fashion wherein all regulatory functions are distributed amongst authorities who may delegate it to functionaries lower down the order in terms of execution. In case of any jurisdictional conflicts or those regarding interpretation of rules—there are clear conflict rules that come into operation and such conflicts are usually referred to an another authority higher up in the chain of command. This is in stark contrast to decentralized modes where regulatory authority is heterarchically arranged and where mandates may overlap in the absence of clearly laid down jurisdictions and conflict rules.[16] The involvement of technical experts from the private sector results in the development of decentralized governance structures and the construction of new professional regulatory cultures. Professional associations of doctors, accountants, lawyers, scientists, managers and economists—in many ways constitute a new *cadre class*[17] that participate in regulatory activities. Their participation has become necessary because of the complexity of social life—differentiated into spheres of logic and action.[18]

This is reflected in the division of the legal order into specialized sub-fields. International law is of course characterized by a lack of central ordering—but this specialization—has become more pronounced by the production of norms by private actors either through formal delegation[19] or in other cases according the norms generated by them *ex post* recognition.[20] Within international law, this has led to fears of fragmentation in absence of clear rules of conflict given the

[14] de Chazournes (2012), pp. 479–481.

[15] Turner (2008) at 160.

[16] Heterarchy is a term used to characterize different forms of horizontal and vertical relations between the regulation regimes where mixed and that horizontal structures dominate. For instance the standardization of safety requirements related to products, which is primarily provided on the basis of cooperation between private and public actors. In this example, hierarchic legislation plays only a role when it comes to the incorporation of private standardization into law. See Teubner (1997a) and Kooiman (2003).

[17] I use this phrase 'cadre class' deliberately to allude to Max Weber's use of the term to predict increasing differentiation of social spheres and therefore the trend towards specialization.

[18] Van Der Pijl (1998).

[19] For instance the Technical Barriers to Trade Agreement recognizes the ISO as a valid source of international standards and therefore create a presumption of conformity with the Agreement in case of member states taking measures that concern public health and safety.

[20] For instance the *New Approach* Directives in the European Union recognize international standards that are formulated by the European standard organizations as 'harmonized standards' that carry a presumption of conformity. E.g. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

non-hierarchical setting.[21] This notion of fragmentation through 'expertization'[22] primarily illustrates the idea that the unity of the legal order[23] will be undermined and thereby the certainty, predictability, coherence and consistency of the legal relations. In other words this would result in regulatory gaps and uncertainty and thereby challenge legal certainty.[24]

The other important and perhaps expected consequence of such developments that have animated legal theorists is the issue of legitimacy and accountability deficits.[25] Law derives its authority from the *ex ante* democratic legitimacy that empowers rule makers to make rules. Moreover accountability of public actors is ensured through numerous *ex post* administrative rules that govern public decision-making. Both these aspects are however structurally unavailable for private actors that participate in regulatory activities.

In the following sub-section, I discuss the major theoretical expositions that have taken cognizance of these horizontal and vertical developments and have sought to address them by devising, formulating and creating new theoretical concepts and reshaping some old concepts. The objective here is to provide an overview of the response from legal theorists to these developments. Keeping in mind that there are primarily two theoretical implications posed by these developments—that of a challenge to legal certainty and to legitimacy and accountability—this would also allow me to clearly identify the quality and depth of attention paid to each of these two problem areas. And, thus I hope to clearly underscore the relevance and the *raison de etre* for writing this book.

1.2 Theoretical Landscape of Legal Responses

How have legal theorists reacted to these developments? These developments have questioned our conventional understanding[26] of the nature of law, the functions of law and the fundamental characteristics of the legal order. I will focus attention on

[21] Koskenniemi and Leino (2002), pp. 553–579; Koskenniemi (2007), pp. 1–30.

[22] Koskenniemi (2009), pp. 7–19. Teubner and Fischer-Lescano (2004), pp. 999–1046.

[23] An interesting European research project is the COST Action on 'Fragmentation as Expertization: Rethinking the Fragmentation and Constitutionalization of International Law.' The project leaders contend that "The specific legal regime co-determines the framing of the questions posed to experts, the ways to assess scientific outputs and the manner in which scientific insights are translated into legal and political decision-making. The increasing technocratization and legalization of politics is accompanied by an increasing diversification in the production, assessment and application of (legal) knowledge." See project webpage: http://www.il-cf.eu/index.php?option=com_content&view=article&id=20&Itemid=24 (last accessed 4 March 2013).

[24] Werner (2007), pp. 17–30.

[25] See for both a theoretical analysis and a descriptive overview of such developments; Pauwelyn et al. (2012) and Berman et al. (2012).

[26] By conventional understanding—I refer to the legal positivist view of law that have focussed on the internal structural dimension of what law is and thus what the legal order looks like. Starting

two sets of approaches that have engaged directly with these developments. The first set, represents a search for unity in the face of these developments—and in the process reaffirms the idea of a coherent and consistent (if not hierarchic) legal order. International constitutionalism and 'global administrative law' (GAL) are two such approaches. The second set approaches include legal pluralism and systems theory—that are based on the presumption that society is characterized by multiple systems of social ordering—and law is just one of many concomitant systems. I have chosen to focus attention on these two sets of approaches; viz. international constitutionalism, GAL, legal pluralism and systems theory; precisely because all of them have seek to explore, explicate and develop theoretical concepts to address these developments. Together therefore they provide a valuable foundation to my own explorations into legal certainty in the context of these developments.

1.2.1 International Constitutionalism and Global Administrative Law

Scholars advocating International constitutionalism have underlined the need for a system of horizontal values that could bring some unity and coherence in the face of fragmentation. Both procedural values such as fairness and justice as well as expanding on the more substantive values of *jus cogens* have been suggested as a meta rule for ensuring if not convergence at least co-existence of closed international and autonomous legal orders (e.g. World Trade Organization).[27] Others have also taken this opportunity to also look inwards as to the ideas of constitutive power and legality[28] and the continued problem of sovereign boundaries as an impediment to the pursuit of global justice[29] and also in evolving a constitutional consensus in specific international legal regimes; given that sectoral fragmentation is also another aspect of international law.[30] Development of non-statist 'legal'[31]

with Austin's theory of law as the command of a sovereign, which were backed by the threat of sanction; to Kelsen's pure theory of law which traced all legal rules to a *grundnorm* that sat atop of a hierarchy of all lower legal norms; to Hart's distinction between primary and secondary norms and the idea that law is not followed because of the threat of coercive sanction but because of an internal sense of obligation. It is the study of the internal structure of the legal order that distinguishes theorists in the legal positivist tradition from theorists like legal pluralists that look at law from an external perspective. See Austin and Rumble (1995); Kelsen (1967); Raz (1979) at 122–145; and Hart (1961).

[27] See Walker (2002), pp. 317–359; Dunoff and Trachtman (2009); Klabbers (2004), pp. 31–58; and de Wet (2006), pp. 611–632.

[28] Dyzenhaus (2012), pp. 229–260.

[29] Follesdal (2012), pp. 261–277.

[30] Heller et al. (2012), pp. 278–312; and Jillions (2012), pp. 429–454. Havercroft (2012), pp. 120–140.

[31] I use the term 'legal' to refer to some form of private ordering of value systems—that reflect the interests and objectives of actors structuring and operating these regimes.

regimes such as *lex mercatoria*,[32] internet regulation by ICANN[33] and global supply chain management by multinational corporations have also exacerbated this process of fragmentation and non-communication that is anathema to the developments of meta rules.[34] One important characteristic that defines studies on international constitutionalism is the preponderance of international legal orders that are linked to statist initiatives as differentiated from transnational governance regimes that are beyond the nation state. Studies of international constitutionalism have therefore been coloured by statist impulses that are necessarily aligned to the notion of a sovereign nation state. This has also been evident in the cross currents of opinion that discuss this bias within international constitutionalism.

In an edited collection of articles in their book[35]—*Ruling the World*—scholars Jeff Dunoff and Joel Trachtman view international constitutionalism in purely instrumental and minimalistic terms, as that which influences the production of international law. Thus international constitutionalism is an internal process and imperative of international legal orders and regulatory regimes that should be judged in its own terms—as either enabling or impeding the pursuit of global public goods. On the other hand, Neil Walker is far more critical of the usage of the term 'international constitutionalism.' He discusses how the term is embedded within liberal democratic political theory discourses of the nation state. And therefore the usage of the term necessarily alludes to the values that are enshrined—rule of law, democratic deliberation and protection of rights—and which act as limitations on the powers of the state. Thus, within the international domain the adoption of the term is not value free but value laden. He evocatively poses the question: 'can the rise of a new constitutionalism be an answer to the decline of the old constitutionalism?'[36] The argument forwarded here is that given that domestic constitutionalism tied to nation state seems to be increasingly challenged by international processes and actors involved in law-making activities that are beyond the nation state—does international constitutionalism's—search for the identification of global public values (most famously enshrined through *jus cogens* principles)—seek to replace domestic constitutions within nation states? The presumption here is that international constitutionalism is not a benign theoretical tool—but a decidedly political enterprise—that seeks to push the adoption of a certain kind of liberal political values—which may be used to restrict the power of states to pursue their own national policies.[37]

The GAL project, on the other hand focuses on non-statist developments—developments that are fuelled by private actors.[38] Taking off from an administrative

[32] Michaels (2007), pp. 447–468.

[33] See Goldsmith (2000); and Mayer (2000), pp. 149–169.

[34] Abbott and Snidal (2009).

[35] See Dunoff and Trachtman (2009).

[36] See Walker (2009).

[37] Walker (2011), pp. 369–385 and Walker (2008), pp. 519–543.

[38] For an interesting comparison of the two approaches see Ming-Sung (2013), pp. 437–468.

law paradigm, specific attention is paid to augmenting the legitimacy and accountability of these international processes. The emphasis is on identifying and developing mechanisms for improving deliberative processes within regulatory spaces[39] populated by both private and public actors within international organizations. Unlike in the case of international constitutionalism, GAL scholars have made efforts in recording instances of GAL through case studies and attention has now shifted to the 'internal side of law'—procedural aspects in identifying common concerns that processes producing GAL need to address. This is in marked contrast with constitutionalism where attention is more on the external dimension of legitimacy of law—through a higher political text.[40]

GAL scholars do not differentiate between distinct levels or even types of regulation i.e. private and public, local, national, international.[41] Instead they subsume all regulation under the moniker, 'administration' that is taking place in the global administrative space. This global regulatory space is populated by a gamut of actors that have little in common in terms of institutional structures and functions except that they operate within this space. This includes international institutions, regulatory networks and domestic administrators that operate within regional/international legal frameworks.[42] The sheer variety of actors includes entities that are private, public and also private–public partnerships with hybrid governance structures. Governance is mostly decentralized and not controlled by a single entity and therefore although there is possibility for collaboration it may at times also lead to duplication, concurrence and competition. More interestingly GAL scholars also underline the fact that not all actors functioning within this regulatory space are 'willing participants'—they give the example of domestic courts who are frequently confronted with legal disputes and issues—that are primarily triggered by ruptures within this global regulatory space and therefore much beyond the remit and jurisdiction of domestic courts.[43]

The major focus of GAL scholars has been to first map the scale, dimension and features of the phenomenon and then more importantly to explore and evaluate legal mechanisms, regulatory principles and sectoral practices that affect or directly address the accountability and thereby legitimacy[44] of these processes. Thus issues like transparency and public participation in decision-making, rationality and legality and review of decision making have been at the heart of GAL discussions. The first wave of studies on GAL adopted a case study approach of explicating the

[39] The term 'space' as used in the context of GAL is similar to the theoretical construct of 'regulatory space' as developed by Hancher and Moran. See Hancher and Moran (1989) at 271–299. This is a key concept used in this book; see footnote 70 in this chapter for a brief description of the concept and how it is used in this book.

[40] Ladeur (2009).

[41] Kingsbury et al. (2005), pp. 15–62.

[42] See for instance; Zaring (1998), pp. 292–297; Kalypso and Shaffer (2005), pp. 263–317.

[43] Lang (2008).

[44] For an interesting discussion of the theoretical implications of choosing different accountability mechanisms and whether legal accountability serves as an alternative to democratic accountability, see Stewart (2008).

phenomenon and the search for commonality and unity between the instances and was therefore decidedly inductive in its orientation.[45] However recently there has been a move towards building a better theoretical understanding of GAL. One such promising effort[46] has been made by Benedict Kingsbury by elucidating the criterion of 'publicness'.[47] The concept of 'publicness' is used here to convey the understanding that law-making is addressed towards the *public* and therefore should fulfil the aspiration of being applicable and of use to the public. Kingsbury argues that increasingly one is able to discern a commitment to 'publicness' by actors in the field of GAL. In the form of a direct or indirect commitment or even as aspiration to fulfil some demands of legality, rationality, proportionality, rule of law and recognition of certain basic human rights. This imperative is what characterizes GAL actors.[48]

1.2.2 Legal Pluralism and Systems Theory

The second sets of responses are those that advocate the idea of legal pluralism.[49] Legal pluralism is based on the premise that state law is not the only source of legal norms. Legal norms may also be sourced from other systems of social orderings viz. religion, culture, community, etc.[50] Once we move away from the shadow of a "legal order" or even "legal orders"—parallelism of normative value systems seem intuitively attractive and even acceptable in the context of international law.[51] However this does not mean the abandonment of a search for order. Order is sought to be maintained not through an established hierarchy of norms—but via a system of conflict rules that allow for interaction between the normative orders and resolution in cases of conflict.[52] An approach which is similar to the conflict of law rules that

[45] See Cavalieri et al. (2012).

[46] Other efforts include; Krisch (2009a); and De Burca (2008), pp. 101–158.

[47] Kingsbury (2009), pp. 23–57. See also von Bogdandy et al. (2010).

[48] Another important conceptualization of these processes has been the project on 'Informal International Law Making' (see Pauwelyn et al. 2012 and Berman et al. 2012). Informality of these processes has been captured through the aspects of output, processes and actors involved. Reasons for proliferation of such processes are also discussed. Most pertinently, the authors argue that lack of democratic legitimacy in such processes can be countered by procedural meta norms—referred to as 'thick stakeholder consensus' that act as review mechanisms for actors, processes and output. They suggest that as a benchmark this could be normatively superior to "thin state consent" which is the fundamental validation for international law.

[49] Studies on legal pluralism were developed to explore non-legal normative systems that may operate alongside law in the context of nation states. However the same conceptual framework has been applied in the context of international context.

[50] See Merry (1988), pp. 869–901; Moore (1973), pp. 719–746; and Griffiths (1986), pp. 15–29.

[51] Zumbansen (2010), pp. 141–189.

[52] Berman (2007), pp. 1155–1237; Burke-White (2004), pp. 963–979; Twining (2009), pp. 473–518.

operate within private international law. Private international law has also served as an inspiration for applying the conceptual framework of interlegality[53] to transnational governance as an arena for productive normative contestation.[54] The goal of such approaches has been to unearth evidence of concomitant normative systems and explore ways in which these systems interact and communicate.

The systems theory of law, argues that modern society is divided into functionally differentiated sub systems—viz. law, religion, politics, economics.[55] Law as a separate system of social ordering—is characterized by a distinct binary code (legal/illegal) and a conditional program. Each social ordering also develops its own specialized communication systems. These systems exists concurrently and are open to influence by each other—so they share a heteronomous relationship and communicate with each other through what is referred to as 'structural coupling'.[56] Thus there has been an expansion of private and 'unofficial' legal orders that cater to specific sectors—the internet, sports organizations, private investment, and commercial transactions—and generate norms within functionally self-sustaining normative orders. Gunter Teubner has further developed this theory by proposing for social constitutionalism as a normative corollary to greater differentiation and rationalization in world society.[57] The process of juridification of autonomous institutional spheres will result in different civic constitutions.[58]

However the use of term 'constitutionalism' has been criticized by Nico Krisch, who while agreeing with Teubner on the greater differentiation within society (refers to it as 'post national society')—highlights the weakness of idea constitutionalism itself—the idea of an overarching framework with ultimate authority.[59] Underlining the strength of a pluralist order in terms of adaptability, space of contestation and the checks and balances between different legal systems—he hopes that self-legislating equals can order the political space through deliberative processes that would ensure a balance between inclusiveness and particularity.[60] The problem though, that continues to haunt legal pluralism as well as systems theory discourses, is the criteria to differentiate normative systems or legal orders—lack of a demarcation criteria means that all social norms are recognized as potential legal norms—i.e. they operate and exists in a stand-alone system of normative ordering. This seeks to explain as much as it confounds.

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[53] de Sousa Santos (1987), pp. 279–302. de Sousa Santos (2002).

[54] Wai (2008), pp. 107–128. Also see Michaels (2005), pp. 1209–1259.

[55] Luhmann (1977), pp. 29–53. Luhmann (1985, 2004) and Teubner (1993).

[56] Structural coupling in this regard is referred to as 'zones of contact' in specific instances through which autopoietic systems may communicate and interact with each other. See Nobles and Schiff (2012), pp. 265–269.

[57] See Teubner (2002) at 311.

[58] Teubner (2004), pp. 3–28.

[59] Here it is important to point out—that Teubner's idea of social constitutionalism refers to the process of reification of values within normative orders in society. Therefore society would be many such constitutions operating concomitantly. This is different from Krisch's idea of constitutionalism to mean one overarching framework of values that governs society.

[60] Krisch (2009b, 2012).

The essential difference between legal theorists working within the theoretical frameworks of legal pluralism and systems theory from those working with categories such as international constitutionalism and GAL, is the primary presumption from whence both start. Whereas the former allows (and is therefore comfortable with) for multiple sets of normative orderings and the ruptures therewith and is content to explore some form of rudimentary conflict rules to enable communication and interaction between seemingly closed normative orders; the latter is keen on developing meta rules—be that in the form of substantive meta rules (e.g. *jus cogens*) or procedural safeguards (viz. 'publicness' criteria) to address accountability deficits.

1.2.3 Spotlight on an Under-Researched Issue

As I have mentioned in the concluding sentence in Sect. 1.2, together these two sets of approaches provide valuable foundations to my own explorations on legal certainty. This includes the appreciation of the pluralist nature of such processes. Thus apart from the fact that these processes fall outside the formal legal order—there is little commonality in the institutional structure, processes and the nature of actors involved. Further the review of these approaches makes it apparent that aligning with the dichotomy of international and national legal orders is of limited purchase and it makes far more sense to study these processes in the context of domain/issue specific 'regulatory spaces'. Thus the unity of legal orders reflect an academic aspiration rather than an approximation of reality.

As I have explained at the end of Sect. 1.1, there are primarily two theoretical implications of the horizontal and vertical developments that are shaping the world—issue of legal certainty; and that of legitimacy and accountability. In the following paragraph I briefly explicate these two implications.

Legal positivists explain legal certainty—in terms of predictability, certainty, coherence and consistency of the legal relations in society—this is ensured through a hierarchical system of normative ordering—characteristic of national legal orders.[61] The idea of hierarchy encapsulates the possibility of identifying always a higher rule in case of norm conflict or reference to an authority with powers to give conclusive rulings on such conflicts and thereby ensuring juridical unity of the legal order and reducing (if not eliminating) uncertainty and ensuring legal certainty. Globalization has challenged the sanctity of national legal orders.[62] Although structurally domestic legal orders continue to exist, they increasingly interact and respond to other specialized normative orders that focus on specific sectors. These normative orders function alongside and interact with national legal orders (and in some cases may penetrate them) and heterarchy rather than hierarchy seems to be a more apt description of the nature of the relationship between these

[61] Pino (1999), pp. 513–536; and Christiano and Sciaraffa (2003), pp. 487–512.

[62] See Mac Cormick (1999) and de Witte (2003).

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