1. Introduction

We eat them. We breathe them. They seep into our skin without our knowledge or permission. Every day, we come into contact with hundreds of natural and synthetic chemicals and we know almost nothing about what they may be doing to us. Of the more than 100,000 chemicals on the EU market, it is estimated that around one third likely result in little exposure and another 20 per cent or so only present minimal risks. This leaves over 40,000 chemicals to which we are exposed and which may pose a more than minimal risk. By 2007, less than 1 per cent of all chemicals on the market had been tested by state regulation, with industry having voluntarily tested a mere 80 substances between 1995 and 2005. Since then, some progress has been made, but we still live largely in a world of ‘toxic ignorance’. While it is difficult to quantify the myriad harms from chemicals, the World Health Organization has estimated that 5 per cent of the global burden of disease can be attributed to chemical exposures. This equates to around three million deaths per year.

The aims of EU chemicals legislation have been to generate much needed information about impacts (on human health and the environment) and to protect against potential harms. To these ends, the EU has adopted a host of legislative instruments, each with different features, but all contributing

1 A small part of this chapter appears in print as: Elen Stokes and Steven Vaughan, ‘Great Expectations: Reviewing Five Decades of EU Chemicals Control’ 25(3) Journal of Environmental Law 411.


to the control of chemicals across a range of commercial sectors. This book is concerned with REACH, the EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals, which came into force in 2007, and its regulator, the European Chemicals Agency (‘ECHA’). REACH is the flagship of the EU’s regulatory regimes for chemicals and was intended to mark a stark departure from previous legislation.

The text of REACH stands at more than 130,000 words. The most recent consolidated version of the Regulation is 516 pages long. Indeed, it is one of the longest legislative instruments in the history of the EU; almost a third longer than the consolidated version of the TFEU. For the uninitiated, REACH is a daunting and intimidating piece of legislation, requiring an ability to speak the language of toxicology. There is little by way of significant academic writing on this Regulation, quite possibly because of its sheer size and, for those not so engrossed by science or the minutiae of risk assessment, chemicals regulation may appear dull and impenetrable. An effective understanding of REACH, however, stretches far beyond knowledge of the Regulation. Accompanying the text of the legislation are a further 5000 pages (more than 1,000,000 words) of guidance produced by the European Chemicals Agency, to say nothing of the other normative framing and shaping documents (some labelled ‘guidance’; some not) issued by other public bodies (e.g. the EU Commission and Member State competent authorities such as the Health and Safety Executive in the UK) and private actors (industry associations, NGOs, law firms, consultancies etc.). The use of guidance to accompany legislation is hardly a new phenomenon, but the breadth, formats and depth of guidance that accompanies REACH, and the functions that guidance serves, are striking.

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This book is a study of norms. My aim is to use REACH to show how soft law (norms which, while they may have significant practical effects, are usually said not to be binding) can be just as differentiated, plural, hierarchical, persuasive and complex as hard law (treaties, legislation etc.). Soft law has primarily been seen as something monolithic and also as something which sits alongside, or operates in place of, hard law. This book is concerned with hybridity, a concept that has been used in a number of situations. For regulation scholars, a hybrid is seen where regulation is multi-modal (blending, say, command and control approaches with self-regulation) and/or where public and private forms of regulation co-exist. For governance scholars, a hybrid occurs where hard and soft law complement each other, occupying the same field to promote the same goals. This book is primarily concerned with the latter, the situation in which hard and soft norms are ‘yoked’ together, one of a number of outcomes of a shift towards ‘new governance’. These new governance approaches, in the EU and elsewhere, have emerged as policy makers respond to changes in society, in the economy (financial and political) and to innovations in public administration. De Búrca has suggested that the rise of new governance systems can be seen as a response to two background conditions: the first is ‘the need to address complex policy problems which have not shown themselves readily amenable to resolution’; and the second is the need to manage interdependence where divergent national regulatory regimes affect one another. REACH is a strong example of the former; and less so of the latter, given the existence, pre-REACH, of EU chemicals control schemes, albeit not very effective ones. The history of EU chemicals regulation is set out in Chapter 2.

13 Gráinne de Búrca and Joanne Scott, ‘Governance, Law and Constitutionalism’ in Gráinne de Búrca and Joanne Scott (eds), Law and New Governance in the EU and the US (Hart 2006).
14 Trubek and Trubek (n 12); de Búrca (n 12) 232.
As a field of study and a phenomenon, ‘new governance’ seeks to explore, understand and critique changes in EU governance as they move away from traditional, top-down, command and control modes of regulation (associated with the Community Method) and towards deliberative, diverse, flexible, decentralized, experimental, multi-level, reflexive and participatory forms of decision-making. Or, as Armstrong frames it, ‘new governance’ seeks to provide a legal response to the proliferation of modes of governance and to explain how these changes signal, ‘the decline of a traditional world of hierarchical governance’. This book shows how newer modes of governing, via post-legislative soft norms, may simply be replicating that traditional world of hierarchy. So, what we see are multiple forms of (soft) ordering, in different formats (guidance, ‘quasi’ guidance, FAQs etc.), originated by different authors (some public, some private) with varying levels of depth, precision and specificity. Much of the work on new governance to date has consisted of mapping exercises using specific case studies, or (less empirically grounded) work charting the normative aspects of the new and emerging governance patterns. This book is, in some ways, another case study mapping project. However, it is the detailed mapping of the contours of the operationalization of REACH, via the legislation and its accompanying guidance, that have highlighted nuances within, and challenges to, current understandings of EU governance. As de Búrca has noted, ‘if we are to understand [new governance] change, there is no substitute for careful and thorough research’.

My work on REACH in this book is aimed at two distinct groups. The first group to whom this book is addressed are the legal practitioners, consultants, academics, policy makers and others who are searching for a comprehensive and accessible exposition of REACH and a better understanding of how the wealth of guidance on the Regulation fits with the legislation. It is hoped that this book will act as a departure point for further work on EU chemicals regulation. The second group to whom this book is

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17 Armstrong and Kilpatrick (n 15) 652.

addressed are those interested in new governance and modes of regulation, both as academic sites of study and as the practical sites of exploration of ‘what works’ for policy makers, regulators, industry and others.

**SOFT LAW AND THE EU**

In the EU context, the classic understanding of ‘soft law’ comes from Snyder who described it as, ‘rules of conduct which in principle have no legally binding force but which may nevertheless have practical effects’.19 Lee writes that soft law instruments are ‘likely to have’ the endorsement of a community institution, but lack the formality required by the Treaty as regards law making.20 A decade later, and building on Snyder’s work, Senden offered up this amended definition of soft law, ‘rules of conduct that are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain (indirect) legal effects, and that are aimed at and may produce practical effects’.21

The purpose of defining ‘soft law’ is often to differentiate it from and draw a line between it and ‘hard law’. However, as Kirton et al observe, ‘Both terms [hard law and soft law] are used with a great variety of meanings in the existing literature.’22 Given the varying and numerous attempts to ascertain the exact nature of ‘soft law’, there seems little point in setting out a ‘non-exhaustive miscellany of descriptions’.23 While Shaffer and Pollack counsel that confusion and disagreement about the basic characteristics of hard and soft law may mean that, ‘scholars in many instances speak past each other’,24 getting agreement on one definition and one understanding seems highly unlikely. Senden, meanwhile, argues (and I would agree) that the notion of ‘soft law’, ‘provides a maybe not perfect,
but at least reasonably satisfactory umbrella concept’. For present purposes, ‘soft law’ is used in this book to describe governance arrangements that operate in place of, alongside or blended with EU ‘hard law’ in the form of the treaties, regulations and directives and the Community Method. The hierarchy of EU norms is explored in more depth below.

Soft law has been applied to a number of settings in the EU since the 1980s. In the last decade alone, we have seen discussions of soft law in relation to EU instruments on state aid, EU fiscal governance, the open method of co-ordination, EU employment policy, EU integration and accession, EU competition law, EU governance of retailing, control of new and emerging technologies within the EU and EU tax law. However, many of the soft law examples used in the literature act either in the place of hard law or alongside hard law; few discussions concern where soft law is often foreseen by, and used to build on, hard legislation. There is comparatively little work on hybridity, and none as rich as that offered up in this book. The existing literature is thus largely focused on researching and understanding soft law as something pre-legislative or extra-legislative, with little attention to the role and functioning of soft law as post-legislative.

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25 Senden (n 10) 110.
26 Trubek et al (n 11) 1.
27 Senden (n 10) 109.
30 David M. Trubek and Louise G. Trubek, ‘Hard and soft law in the construction of Social Europe’ (Presentation at the workshop “Opening the Open Method of Coordination”, Florence: July 2003); Armstrong and Kilpatrick (n 15).
34 Duncan Matthews and David G. Mayes, ‘The role of soft law in the evolution of rules for a single European market: The case of retailing’ (National Institute of Economic and Social Research Discussion Paper No. 61, 1995).
Introduction

For present purposes, this book’s parameters follow Senden’s broad definition: ‘Soft post-legislative rule making concerns acts that provide further general rules and guidance to national authorities and interested parties on the proper interpretation, transposition, application and enforcement of already existing EU law.’37 These instruments fulfil what Senden referred to in her earlier work as a ‘post law function’.38 Soft post-legislative instruments can take a variety of forms and may be called a number of different things: guidelines, notices, letters, communications, codes etc.39 In this book, ‘guidance’ is used as a shorthand overarching term to encompass those soft post-legislative instruments that are called ‘guidance’ and those (discussed, in the context of REACH, in more depth in Chapter 4) which are called something else (e.g. formats, nutshells, technical guides, FAQs) but which fulfil the same function. In many ways, it is the plurality of the forms of post-legislative guidance that make the subject so interesting and which raise important questions about differentiation and hierarchy. These are discussed in detail in Chapter 9.

HIERARCHY AND DIFFERENTIATION IN EU NORMS

For the first time since the establishment of the European Community, the Lisbon Treaty sets out specific areas of competence for the EU: those areas where the EU alone has competence; those where competence is shared with Member States; and those areas the exclusive domain of the Member States.40 Where the EU has competence, there are a range of regulatory instruments that can be brought to bear.

EU law comprises primary legislation (the Treaties), secondary legislation (Regulations, Directives and Decisions) and case law. Regulations are binding legislative acts that apply in their entirety across the EU, without the need for Member States to amend their bodies of national law.41

38 Senden (n 10) 143–4.
41 Article 288 TFEU (formerly Article 249 TEC).
Directive are binding as to the result to be achieved, but leave the form and means of achievement open to Member States. Directives are implemented via Member States amending their bodies of national law. Decisions are directly binding on those to whom they are addressed (e.g. a particular Member State, body corporate or individual). The Treaties also refer to Recommendations and Opinions. Recommendations (which suggest a course of action) and Opinions (which are effectively statements by the EU institutions) have no binding force. In addition to these instruments which are set out in the Treaties, there are also a wealth of ‘rules, manuals, directives [with a small “d”], codes, guidelines, memoranda, correspondence, circulars, protocols, bulletins, employee handbooks and training materials that clutter the desks (and computer files) of EU bureaucrats’. As Senden has observed, ‘the catalogue of sources and hierarchy of norms in Articles 288 to 291 of the TFEU are of misleading simplicity’ and belie the many other instruments that emerged in the EU’s institutional practice over time. This is equally true in the context of REACH: the vast expanse of the Regulation belies what guidance lies beneath.

The EU is an institution grounded on and in hard law. Historically, the EU has worked on the basis of top down, hierarchical, binding norms (Regulations and Directives) as a means of harmonization: the classic command and control model of regulation operationalized via the Community Method. Over time, however, and as seen in other national and supranational contexts, the variety of regulatory modes (economic regulation, self-regulation, informational regulation etc.) and regulatory approaches has proliferated. In its 2001 White Paper on European Governance, the Commission was of the view that a combination of different policy instruments was key to effective decision-making and the meeting of Treaty objectives. They also suggested that ‘legislation is only part of a broader solution combining formal rules with other non-binding tools such as recommendations, guidelines or even self-regulation within a commonly agreed framework’.

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42 Ibid.
43 Ibid.
44 Ibid.
46 Senden (n 37) 57.
47 Kirton and Trebilcock (n 22) 347.
48 Commission (n 2) 20.
49 Ibid.
POST-LEGISLATIVE GUIDANCE

There has been a notable increase in the use of legislative guidance in the EU, both generally and specifically in the context of EU environmental law. This, Scott observes, is a product of increasing legislative complexity and a marked reliance on broad and imprecisely defined framework norms. Post-legislative guidance in the EU is a form of soft law in that it is a governance arrangement that operates alongside or is blended with EU ‘hard law’ that comes from the treaties, and secondary law adopted under the Community Method. The work in this area splits primarily between those who observe this shift as an indicative development in the maturing EU legal landscape, and those who raise objections to its use (as regards transparency, accountability and competence creep). This book, as set out in Chapter 10, aligns more with the former view than with the latter.

There are two ironies at play here: first, new governance forms were said to emerge because of legitimacy concerns with the classic Community method, but these newer forms of governance themselves pose legitimacy challenges which often replicate those seen before, problems with: participation; accountability; transparency etc. These are discussed further in chapters 9 and 10. The second irony is that the EU has striven over time to become a valid legal order and, in many ways, to mirror the legal orders of its Member States – in using soft instruments (as have been previously, and still are, used in the Member States) the EU both matures as a legal order (as that order reflects the variety and constellations of norms in the Member States), but also opens itself up to claims that its legal order is fragile and illegitimate because it contains soft instruments.

Much of the early work in the new governance field is on contrasts: on setting out and exploring the dichotomies between old and new governance, between hard and soft law. As such, new governance scholarship has been criticized for its ‘definition-by-contrast’ approach and for idealizing the ‘new’ over the ‘old’. This is in spite of the origins of this body of

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51 Trubek et al (n 11) 1.
52 See the review here: Senden and van den Brink (n 37) 15.
53 The best starting point for a greater discussion of these (and other) criticisms is: Jan Klabbers, ‘The Undesirability of Soft Law’ (1998) 36(1) Nordic Journal of International Law 381.
54 Scott and Trubek (n 15) 17.
55 On the former, see: Gráinne de Búrca and Joanne Scott, ‘Introduction’ in Gráinne de Búrca and Joanne Scott (eds), Law and New Governance in the EU and US (Hart 2006). On the latter, see: Armstrong (n 16).
scholarship in offering up a critical review of the ‘normative qualities of different “old” and “new” forms of governance in the EU, and their compatibility with the principles of the rule of law and democracy’. More recent work, however, suggests that such a binary distinction does not account for variations in policy development, implementation, assessment and justiciability of various instruments. While dichotomies provide clear bright lines, and as such are attractive, there is a risk that these binary understandings ‘undersell and under-explain’ changes that are occurring in the functions and definitions of law and governance. The exploration of REACH in this book suggests that a harder look at soft norms will help to show that the bright lines are not so bright, and that a closer look at notions of hybridity is important. As Armstrong persuasively argues, identifying differentiation in EU law is much more important than simply charting a shift from traditional towards newer forms of governance. He writes that the EU is a ‘striking illustration’ of a phenomenon which sees ‘pluralisation and differentiation in the techniques, tools and methods deployed by public and private actors in the search for more legitimate and/or more effective means of securing economic and social governance’. This book focuses therefore upon the plural, differentiated hybrid of new governance and the Community Method. Here, we have an EU Regulation that contains both framework norms and detailed commands alongside a wealth of post-legislative framing documents, in the shape of guidance. It is important to move the debate beyond the existing, somewhat blunt typologies of soft norms that have compared ‘preparatory and informative instruments’ and ‘interpretable and decisional instruments’; or ‘soft regulatory rule-making’ (involving para-law policy-steering instruments) with ‘soft administrative rule-making’ (involving post-legislative guidance instruments). The functions, formats and blends of post-legislative norms offered up by this book are set out in detail in Chapter 9. By way of a taste of what is to come, I argue in this

58 Armstrong and Kilpatrick (n 15) 654.
59 Armstrong (n 16) 252.
60 Ibid.
61 Senden (n 10) 118.
62 Senden and van den Brink (n 37) 12; Senden (n 37) 60.
book that post-legislative guidance under REACH shapes the operation of the Regulation in four distinct ways: amplification; standardization; translation; and extrapolation. Amplification occurs where guidance produced by ECHA goes beyond, but is not in direct contradiction with, the text of the Regulation. Standardization is a subset of the amplification function. Here, the goal of ECHA is to channel registrants (and others) down given avenues of action (not set out specifically in the text of REACH) in order to make the tasks for which ECHA is responsible more manageable. ECHA extrapolates in its guidance where REACH is silent on something the Agency thinks is necessary for the effective working of the Regulation. With translation, I argue that while the text of REACH is clear, the Agency, in its guidance, implicitly contests the drafting of the Regulation and ‘translates’ the relevant provisions into something else. While the first two of these actions by ECHA can be seen to be legitimate endeavours of an EU agency (and extrapolation a necessary step for the effective working of the Regulation), the translation function is more troublesome.

**HYBRID LAW**

The potential relationships between traditional and more experimental forms of governance are myriad: they may co-exist in parallel, run counter to each other, overlap or fuse, each to lesser or greater degrees and potentially also in combination. Trubek and Trubek argue that when new governance approaches are ‘yoked together in a hybrid form’ with conventional forms of regulation, we see a ‘real transformation in the law’. These hybrids, they argue, represent a new form of law in which hard and soft norms are fused together and, as such, are ‘of special interest’. While these notions of ‘yoking’ and ‘fusing’ are interesting, and intellectually neat, what we see in REACH (as set out in depth in this book) is actually far more nuanced and far more complex than a simple join: without wishing to belabour to metaphor, what REACH shows are multiple yokes, with interesting variations and gaps in the seams, drawn together by a variety of threads. In the context of EU race discrimination law, de Búrca writes of ‘different approaches yoked together in a single and increasingly integrated

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63 The full spectrum of possible configurations is set out in detail here: Trubek and Trubek (n 12).
64 Ibid, 3 (emphasis as in the original).
65 Ibid 5.
framework’. With REACH, and as set out in the chapters which follow, what we have is perhaps not just a hybrid hard law/soft law approach, but a hybrid regime for chemicals control (hard and soft, public and private, foreseen and not foreseen, multiple, and imperfect).

It is worth noting here that early notions of ‘hybridity’, including those by Trubek and Trubek, and also de Búrca and Scott, use a wider sense of the term ‘hybridity’ to refer to all situations in which hard and soft law complement each other, existing in the same field to promote the same goals (without necessarily being fused or ‘yoked’ together). This book is concerned with the situation when soft norms are yoked with, fused onto, hard legislation. Existing new governance literature focuses largely on researching and understanding soft law as something pre-legislative or extra-legislative, with little attention to the role and functioning of yoked soft law as post-legislative. This is a significant gap in the field given the increasing use of guidance in this way; a gap which this book seeks to part fill.

Trubek and Trubek set out a ‘functional typology’ for hybrid (or ‘transformed’) law. In some cases, laws aim at problem solving or conflict resolution through the creation of new governance procedures. In other areas, law provides recourse to rights when new governance processes fail. Thirdly, new governance may allow actors to exceed minimum standards set down in law, which de Búrca and Scott call

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68 There are only a handful of other works that consider the role of post-legislative guidance in particular regulatory contexts: see Scott (n 9); Senden (n 37); Joanne Scott and Jane Holder, ‘Law and New Environmental Governance in the European Union’ in Gráinne de Búrca and Joanne Scott (eds), Law and New Governance in the EU and the US (Hart 2006); and William Howarth, ‘Aspirations and Realities under the Water Framework Directive: Proceduralisation, Participation and Practicalities’ (2009) 21(3) Journal of Environmental Law 391, 410.
69 Trubek and Trubek (n 12) 10–11.
70 They say this can be seen with the EU’s Environmental Impact Assessment Directive, citing Scott and Holder (n 68).
71 Here, Trubek and Trubek cite the example of the EU’s anti-race discrimination regulation.
‘default hybridity’. Finally, Trubek and Trubek suggest there are cases in which ‘law may provide general norms while new governance is used to help make concrete . . . to give specific meaning to the general norms’. This approach, they argue, is seen in the Water Framework Directive, EU employment discrimination regulation and EU health and safety regulation. REACH shows that this functional typology of hybridity may benefit from further work. To give one example (others are set out in depth in Chapter 9), the hybrid of REACH has emerged both ex ante and ex post: the Regulation, and its drafters, foresaw the need for elaboration of the Regulation, via guidance, and incorporated both specific and general references to that guidance in the legislation (discussed further in Chapter 4); while, at the same time, other actors (public and private), in ways not foreseen in the Regulation, have also contributed to the hybrid nature of REACH (industry, NGOs, Member State Competent Authorities etc.). The hybrids of REACH, plural and plastic, were both planned and not planned, conscious and unconscious, framed and not set. Trubek and Trubek, however, see that the co-existence of new governance and legal regulation ‘may come about accidentally or by design’. This dichotomy does not allow for situations, as seen in REACH, where there is both ex ante planned and ex post ad hoc integration of the legislation with soft law. The integration of EU chemicals governance, from the initial drafting of the Regulation and the REACH Implementation Projects (guidance documents drawn up while the legislation was still being negotiated), to the current multiple modes and forms of norm shaping, is complex. These matters are explored further in chapters 4 and 9.

Whereas, as noted above, much of the work on new governance is about differentiation between different forms of law (hard and soft), it is also suggested that much of the work on hybridity takes post-legislative norms as a fixed phenomenon, rather than, as is seen in this book, themselves differentiated, hierarchical, plural and worthy of close scrutiny. This book is as much about differentiation within soft law as it is about hybridity itself. In so doing, it challenges an assumption that guidance simply adds technical content to legislation; see, for example, ECHA’s risk communication guidance

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72 De Búrca and Scott (n 6).
73 Trubek and Trubek (n 12) 11.
74 The WFD as a hybrid is discussed in Scott and Holder (n 68); and in Ingmar von Homeyer, ‘Emerging Experimentalism in EU Environmental Governance’ in Charles Sabel and Jonathan Zeitlin (eds), Experimentalist Governance in the European Union (OUP 2010).
75 Trubek and Trubek (n 12) 3.
addressed to Member States (discussed in depth in Chapter 6), or the SIEF guidance addressed to registrants (which is far more about collaboration and dispute prevention than it is about the techniques of data sharing – discussed in Chapter 5). The book shows how guidance has the potential to be far more than simply ‘a useful interpretive tool’, in the context of REACH, the guidance effectively operationalizes (to greater or lesser degrees in different contexts) the entirety of the Regulation. My exploration of REACH and its guidance, however, also reinforces some of the core ideas of new governance approaches as flexible, deliberative, diverse and experimental, each to lesser or greater extents as regards different aspects of the Regulation.

For EU scholars, this book also advances understandings about the role of law in the process of EU integration, particularly important in a situation in which ‘the catalogue of sources and hierarchy of norms in Articles 288–291 TFEU are of misleading simplicity’. Much like Lange’s work on EU pollution control, this book pushes our understanding of EU law in context. Law is said to be both ‘the object and the agent’ of European integration. Soft norms could, therefore, be seen as a challenge to the legitimacy that the EU has striven to gain over time. A number of new governance scholars are anxious that (while at the same time wholly cognisant of the limits of traditional forms of EU law) the shift towards new governance approaches might mean that EU law ‘no longer serves as an integrating force in Europe’. Dawson, however, takes a different view: ‘If Europe is no longer being “integrated through law”, soft law instead suggests its integration through functional objectives and outputs – the “completion” of the internal market . . . the achievement of which are sufficient conditions in and of themselves.’

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78 Scott (n 9) 351.
79 Senden (n 37) 57.
80 Bettina Lange, Implementing EU Pollution Control: Law and Integration (CUP 2008).
Concerns as to the EU’s legitimacy as a legal order may have some validity in situations where soft law supplants hard law, or operates in its shadow. However, I would argue that hybrid new governance (where soft law is yoked onto hard law) poses less of a legitimacy challenge to the EU project, and is simply reflective of a maturing legal order. As a consequence, the destabilizing and disintegrative effects of new governance in the EU are arguably less significant with hybrids. This is discussed more in Chapter 10.

BOOK STRUCTURE

Chapter 2 offers the reader an introduction to chemical risk assessment, the chemicals ‘data gap’ and a short history of EU chemicals regulation, including the road to REACH. As was set out at the start of this book, REACH is both complex and lengthy. Because of this, Chapter 3 sets out REACH in sufficient detail for the reader to get a broad sense of how the Regulation works as a whole. This grounding in REACH sets the reader up for the more detailed reviews of individual aspects of REACH that take place in chapters 4 to 8. These five chapters are thick with detail. And unapologetically so. It is only via a careful, thick, rigorous analysis of REACH and its million (plus) words of official and unofficial guidance that the nuanced, complex, differentiated and plural contours of hybrid law become clear. The work set out in chapters 4 to 8 supplies the richest case study on hybridity in more than a decade.

Chapter 4 concerns ECHA and looks at the role and functioning of the Agency and how it produces guidance. It also provides an account of how guidance may be amenable to judicial review by the EU courts, and details how soft law is adjudicated, both in general as post-legislative norms and in the particular jurisprudence on REACH. Chapter 5 unpicks how information is generated under REACH via the formation and operation of mandatory data sharing groupings (known as SIEFs). Chapter 6 then provides an account of Registration (data production and transmission to ECHA) and the wider role of information under REACH. Substance bans and limitations are considered in Chapter 7, and Chapter 8 looks at the enforcement of REACH, which is a matter for Member States. Chapters 5 to 8 each detail and critique the role of guidance in relation to the operation of REACH. Chapter 9 explores, in detail, the differentiation within soft law that is seen with the hybrid of REACH. Chapter 10 then offers up some final thoughts in a short conclusion.