

**Post Legislative Guidance and
European Chemicals Regulation
under REACH**

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SUMMARY

This thesis is concerned with REACH, the EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals, and its regulator, the European Chemicals Agency ('ECHA'). It has two overriding objectives. The first is to provide an exposition of REACH. The Regulation is vast and has been called, "possibly the most controversial and complex piece of legislation in European history", by one of the EU Commissioners who oversaw its genesis. Despite (or possibly because of) this, there is comparatively little substantive writing on REACH.

The second aim of this thesis is to explore REACH using new governance literature and, in particular, writing which looks at post legislative norm elaboration via the use of guidance. The text of the Regulation stands at more than 130,000 words. The most recent consolidated version of REACH is 516 pages long. The Regulation is complex and dense and lengthy. Accompanying this complex legislation are more than one million words of official guidance produced by ECHA. To date, there have been a small handful of case studies which use particular legislative regimes to explore the challenges posed by post legislative norm elaboration via guidance. The yoking of post legislative soft norms to REACH has seen a complex transformation; one which was only partially foreseen in the Regulation (and likely also only partly foreseen in the minds of the legislature). As such, REACH is a good example of an evolving system of EU governance that is both associated with the Community Method and is also differentiated, new, complex and nuanced. However, REACH also acts as a challenge to a number of assumptions in the new governance literature, including: that new governance is non-hierarchical; that yoked soft norms are complementary and come only from the state; and that soft law elaborates solely on framework norms.

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This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any degree or other award.

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For Dad,
I am so sad that you never got to see this

and for Digby,
the proper doctor.

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ABBREVIATIONS

The language of chemicals regulation is at times dense, complicated by a number of acronyms and terms which belie their ordinary meaning. These are not of my own creation, but are set out in statute or various guidance documents. The law under study requires one to know: how ‘IUCLID’ relates to a ‘SIEF’; to be able to identify a ‘CMR’ from a ‘vPvB’; to understand that ‘CSR’ means something other than corporate social responsibility; and that an ‘OR’ is something wholly unrelated to hospitals (unless, of course, negotiations in a SIEF become overly heated). Academics will be glad to hear that ‘REF’ has something to do with enforcement and nothing to do with star ratings. The following list of abbreviations provides an introduction to the main specialised terms and acronyms used in this thesis.

A	
Agency	The European Chemicals Agency
Article	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. While the exact meaning of this term is in dispute, articles are essentially ‘things’ (pens, books, computers) as opposed to chemical substances
Authorisation ¹	Process by which harmful substances are identified and removed from the EU market, while progressively being replaced by suitable alternatives. Includes the possibility for applicants to seek a time limited authorisation to keep the harmful substances on the market
C	
CA	Competent Authority
Candidate List	Substances that may have serious and often irreversible effects on human health and the environment are called ‘substances of very high concern’ (SVHCs). If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorisation List
CAS	Chemical Abstract Service. The CAS maintains the most comprehensive list of chemical substances. Each substance registered in the CAS Registry is assigned a CAS Registry Number. The CAS Registry Number (commonly referred to as the CAS number) is widely used as a unique identifier of chemical substances
CBI	Confidential Business Information
CEFIC	European Chemical Industry Council
CLP	Council Regulation (EC) 1272/2008 on the classification, labelling and packaging of substances and mixtures [2008] OJ L353/1
CMR	Carcinogenic, Mutagenic or Toxic to Reproduction
CSA	Chemical Safety Assessment

¹ It is probably worth noting here that REACH uses the s-pelling and not the z-spelling for ‘Authorisation’. The same approach is taken in this thesis.

CSR	Chemical Safety Report
D	
DNEL	Derived No Effect Limit. A DNEL is the level of exposure to the substance below which no adverse effects are expected to occur
DU	Downstream User. A DU means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. This does not include consumers or distributors
E	
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances. EINECS lists and defines all chemical substances that were on the European Community market between 1 January 1971 and 18 September 1981
Evaluation	Limited assessment of data submitted to ECHA as part of Registration
Existing Chemicals	Chemicals that were reported to be on the market in 1981, when the requirement to notify new chemicals entered into force. There are about 100,000 existing chemicals
G	
GHS	Globally Harmonised System of Classification and Labelling of Chemicals. Developed by the United Nations
GLP	Good Laboratory Practice
H	
HPV	High Production Volume. HPV was used in pre-REACH EU chemicals legislation for substances manufactured annually in volumes of more than 1,000 tonnes. The term is no longer relevant under REACH, but it is currently still use for the global risk assessment of chemicals e.g. by the Organisation for Economic Co-operation and Development
I	
Intermediate	A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance
IUCLID 5	International Uniform Chemical Information Database 5. This software is used by registrants to prepare their registration dossiers under REACH
M	
Manufacturer	Any natural or legal person established within the Community who manufactures a substance within the Community
Monomer	A molecule that can combine with others to form a polymer
MS	Member State
MSCA	Member State Competent Authority

N	
New Chemical	Chemicals that have been placed on the market since 1981. These had to be notified to the Competent Authorities under pre-REACH chemicals legislation. There are around 3,400 'new' chemicals currently on the market
No Longer Polymer	A No Longer Polymer, or NLP, is a substance which was considered as notified under Article 8 (1) of the 6th amendment of Directive 67/54/EEC (and hence did not have to be notified under that Directive), but which does not meet the REACH definition of a polymer (which is the same as the polymer definition introduced by the 7th amendment of Directive 67/548/EEC)
Notified Substance	A substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC. Notified substances also used to be termed 'new substances'
O	
OEL	Occupational Exposure Limit
OR	Only Representative
P	
PBT	Persistent Bio-accumulative and Toxic
Phase In Substances	REACH has a special transitional regime for substances which, under certain conditions, were already manufactured or placed on the market before REACH's entry into force. Such substances are called phase-in substances
Polymer	A substance consisting of molecules characterised by the sequence of one or more types of monomer units
Preparation	A mixture or solution composed of two or more substances
Pre-Registration	Period, between 1 June and 1 December 2008, which allowed potential registrants of the same phase-in substance to get together and submit a registration dossier jointly. Pre-registration was a requisite to benefit from the extended registration deadlines foreseen for these substances
Priority List	Lists of priority substances which require immediate attention because of their potential effects to man or the environment
PPORD	Product and process orientated research and development. PPORD means any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance
Q	
QSAR	Quantitative Structure Activity Relationship. It is the relationship between the physical and/or chemical properties of a substance and their ability to cause a particular effect
R	
REACH	Council Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REF	'REACH En Force'. Projects of ECHA's Forum on Enforcement

Registrant	The manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance
Registration	The submission to ECHA by a registrant of a registration dossier
Registration Dossier	A dossier containing technical data about the intrinsic properties of chemicals. May also contain a CSR
Restriction	REACH process under which limits or bans may be made on the manufacture, placing on the market or use of a substance
RIP	REACH Implementation Project
S	
SAR	A structure-activity relationship (SAR) is a (qualitative) association between a chemical substructure and the potential of a chemical containing the substructure to exhibit a certain biological effect
SDS	Safety Data Sheet
SEA	Socio Economic Analysis
SIEF	Substance Information Exchange Forum
SME	Small and Medium Enterprise
SPORT	Strategic Partnerships on REACH Testing
Substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process
SVHC	Substances of Very High Concern
Substitution	Principle of REACH which seeks to replace harmful chemicals on the EU market with less harmful alternatives
T	
Technical Dossier	Used to refer either to the data required for registration under Article 10(a) of REACH or to one part of the dossier of data required under Annex XV
Tonnage Threshold	Volume based criteria for different requirements under REACH, formulated as "X tonnes/year per manufacturer/importer"
U	
UVCB	Unknown or Variable Composition
V	
vPvB	Very Persistent and Very Bioaccumulative

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CHAPTER 1

INTRODUCTION¹

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% or so only present minimal risks.² This leaves over 40,000 chemicals to which we are exposed. By 2007, less than 1% of all chemicals on the market had been tested by the State as a result of regulatory requirements, with industry having voluntarily tested a mere 80 substances between 1995 and 2005.³ Since then, some progress has been made, but we still live largely in a world of toxic ignorance.⁴ While it is difficult to quantify the myriad harms from chemicals, the World Health Organisation has estimated that 5% of the global burden of disease can be attributed to chemical exposures.⁵ This equates to around 3 million deaths per year.⁶

In 1962, Rachel Carson published ‘*Silent Spring*’, a damning review of mankind’s attempts to dominate nature using synthetic chemicals.⁷ The nightmare in which widespread chemical spraying wipes out insects and birds has not happened, but Carson’s warnings are still highly relevant and, if anything, more urgent fifty years on. The aims of EU chemicals legislation have been to generate much needed

¹ Some 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. For the avoidance of doubt, the only materials taken from the article which appear in this Chapter are those which I authored myself.

² Commission, ‘White Paper on the Strategy for a future Chemicals Policy’ COM (2001) 88 final

³ Liz Stanton, ‘European Chemicals Industry Faces Regulatory Upheaval’ (2005) 7 *Environmental Law Review* 231, 231

⁴ The use of ‘toxic ignorance’ comes from a 1997 report by the Environmental Defense Fund. See: <http://www.edf.org/sites/default/files/243_toxicignorance_0.pdf>, accessed 10 August 2014. For a more recent review of this ‘toxic ignorance’ see: Carl F Cranor, *Legally Poisoned: How the Law Puts Us at Risk from Toxicants* (Harvard University Press 2011)

⁵ World Health Organisation, ‘World Health Report’ (2002) – see: <http://www.who.int/whr/2002/en/whr02_en.pdf> accessed 10 August 2014

⁶ World Health Organisation, ‘Global Burden of Disease’ (2012) – see: <http://www.who.int/topics/global_burden_of_disease/en/> accessed 10 August 2014

⁷ Rachel Carson, *Silent Spring* (Fawcett Crest 1964)

information about impacts 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 to the control of chemicals across a range of commercial sectors. This thesis is concerned with REACH, the EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals,⁸ and its regulator, the European Chemicals Agency ('ECHA'). REACH is the flagship of the EU's regulatory regimes for chemicals and was hoped to mark a stark departure from previous legislation. In many ways, however, this is just the beginning. The story of REACH has some way to go.

This thesis has two key objectives. The first is to provide an exposition of REACH. The Regulation is vast and has been called, "possibly the most controversial and complex piece of legislation in European history", by one of the EU Commissioners who oversaw its genesis.⁹ Despite (or possibly because of) this, there is comparatively little academic writing on REACH. This thesis thus claims part of its originality in providing the first, rigorous and in-depth review of each of the elements of the Regulation. The second aim of this thesis is to explore REACH using literature on hard and soft law and, in particular, writing which looks at post legislative norm elaboration via the use of guidance. The text of the Regulation stands at more than 130,000 words. The most recent consolidated version of REACH is 516 pages long. The Regulation is complex and dense and lengthy. Accompanying this complex legislation are more than one million words of official guidance produced by ECHA.¹⁰ To date, there have been a mere handful of case studies which use particular legislative regimes to explore the challenges posed by post legislative norm elaboration via guidance.¹¹

This thesis argues that while the text of REACH looks complex, much of the operation of the Regulation is framed and given form by the underlying guidance, which at times is more than and at times less than the requirements set out in the

⁸ Council Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [2006] OJ L33/1

⁹ Gunter Verheugen, EU Industry Commissioner
<<http://www.telegraph.co.uk/news/worldnews/europe/1503325/Most-controversial-European-law-wins-parliamentary-approval.html#>> accessed 10 August 2014

¹⁰ See: <guidance.echa.europa.eu/ guidance.echa.europa.eu/> accessed 10 August 2014

¹¹ These are explored in Chapter 2

legislation. This thesis suggests that there are four ways in which ECHA's post legislative guidance shapes the operation of the Regulation. I term these 'amplification', 'standardisation', 'translation' and 'extrapolation'. It is submitted that amplification occurs where guidance produced by ECHA goes beyond, but is not in direct contradiction with, the text of the Regulation. Standardisation is argued to be 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. 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. Finally, extrapolation is said to occur where REACH is silent on something that is necessary for the effective working of the Regulation and ECHA, through its guidance, fills in the legislative gap. While the first two of these actions by ECHA can be seen to be legitimate endeavours of an EU agency, the third is more troublesome. The fourth certainly involves a level of invention on the part of ECHA but, as will be seen in this thesis, there have only been limited instances of extrapolation to date. This thesis also challenges a number of assumptions built into existing scholarship on new governance. It argues that soft law can be just as detailed and as thick as hard law, and that hierarchy and differentiation can be seen in soft norms just as they can in hard. This thesis challenges the assumption that yoked, hybrid (hard and soft) norms come only from public actors and the assumption that yoked soft norms are always complementary to their backstopped hard law. The careful documentary analysis offered up in this thesis is argued to be justification for greater granularity in new governance scholarship and a call to avoid bright line dichotomies. What is seen with REACH is more complex, more nuanced and messier than can be accounted for in simple dyads. Nuance and detail in this context are helpful because they help us to understand exactly what is going on with changes to EU norms, and the development of the EU legal order over time, and such an approach avoids reductive scholarship based on superficial observations of change. Each of these matters is explored in more depth in Chapter 9.

This Chapter begins with a brief overview of modern EU chemicals regulatory regimes. It then sets out the challenges in chemicals risk assessment and management

before turning to the history of chemicals control and, in particular, the history of REACH. This Chapter ends by providing a summary of each of the Chapters which follow in this thesis. It is worth noting at this point that my field of study is the EU. Despite this, the global market (regulatory and industrial) in chemicals is huge. In his review of global trends in chemicals management, Bengtsson identifies upwards of 100 international agreements and programmes on chemicals risk management and monitoring, with a number of mechanisms of international co-ordination.¹² Further work could be usefully done on differentiation and globalisation in chemical norms.¹³

Current EU Chemicals Regulation

Europe, it has been said, is ‘carrying the flag of a chemicals regulatory revolution.’¹⁴ Modern chemicals regulation within the EU is diffuse, the Commission having recently documented 156 separate pieces of existing EU legislation which concern, in some fashion, the control and use of chemicals.¹⁵ As a regulator, the EU is concerned with the intrinsic properties of chemicals (via REACH and via CLP, discussed below), specific sectoral applications of those chemicals (including pesticides¹⁶ and biocides)¹⁷ and with point sources and emissions of chemicals (through rules on waste,¹⁸ water quality,¹⁹ air quality,²⁰ environmental permitting,²¹ etc). More widely,

¹² Gunnar Bengtsson, ‘Global Trends in Chemicals Management’ in Johan Eriksson, Michael Gilek and Christina Rudén (eds) *Regulating Chemical Risks* (Springer 2010)

¹³ Veerle Heyvaert, ‘Globalizing Regulation: Reaching Beyond the Borders of Chemical Safety’ (2009) 36(1) *Journal of Law and Society* 110

¹⁴ Candido Garcia Molyneux, ‘Chemicals’ 5 *Yearbook of European Environmental Law* 327

¹⁵ Commission, ‘Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH: Staff Working Document (SWD (2013) 25 final) 4 (hereafter, the 2012 REACH Review)

¹⁶ Council Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L309/1

¹⁷ Council Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products [2012] OJ L167/1

¹⁸ Council Directive (EU) 2011/65 on the restriction of the use of certain hazardous substances in electrical and electronic equipment [2011] OJ L2011/174

¹⁹ Council Directive (EC) 2000/60 establishing a framework for Community action in the field of water policy [2000] OJ L 327/1

²⁰ Council Directive (EC) 2001/81 on national emissions ceilings for certain atmospheric pollutants [2001] OJ L309/27

²¹ Council Directive (EC) 96/61 concerning integrated pollution prevention and control [1996] OJ L257

the EU also controls impacts from chemicals through import/export,²² product safety,²³ worker protection,²⁴ and food safety regulation.²⁵ Generally (and excluding REACH and CLP), modern chemicals regulation is context-specific, relating, for example, to specific exposure settings (occupational, consumer, environmental) and environmental media (emissions into surface and groundwater, local atmosphere).²⁶ There are, as would be expected, degrees of overlap and ‘double regulation’ between these 156 instruments.²⁷

Since 2007, REACH has been the primary piece of control legislation for chemicals in the EU. At its most basic, REACH requires the generation of data on the intrinsic properties of certain chemical substances (around 45,000 of the 105,000 substances currently on the EU market) by the private sector (namely, the manufacturers, importers and, in limited circumstances, downstream users of those chemical substances) followed by the registration of those substances (accompanied by their testing data) with a new EU regulatory body, ECHA. Certain substances identified (either as a result of industry testing or via Member State nomination) as particularly harmful to human health or the environment will be banned (either in full or in certain applications); others may be granted a time limited authorisation by the Commission to remain on the market if it can be proved that the risks from those substances can be adequately managed, or where the use can be justified on socio-economic grounds and no suitable alternatives are available. Member States have individual responsibility for enforcement of the regime. It is worth noting that REACH excludes from its ambit substances directly regulated by other pieces of EU legislation and substances contained in products which are regulated by specific legislation. A study by Milieu has identified how these exclusions lead to gaps in risk assessment and

²² Council Regulation (EC) 689/2008 concerning the export and import of dangerous chemicals [2008] OJ L204/1

²³ Council Directive (EC) 2001/95 on general product safety [2001] OJ L11/1

²⁴ The starting point here is: Council Directive 89/391/EC on the introduction of measures to encourage improvements in the safety and health of workers at work [1989] OJ L183/1

²⁵ Primarily, Council Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (as amended) [2008] OJ L354/1. For other legislation in this area, see: <http://ec.europa.eu/food/index_en.htm> accessed 10 August 2014

²⁶ It is worth noting here that little has been done as regards EU harmonisation on chemical, and other impacts, to land.

²⁷ These are set out in detail in: Milieu Ltd, ‘Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps’ (Report to the European Commission, 2012) <http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/scope-final-report_en.pdf> accessed 10 August 2014

creates an uneven field in chemical testing and evaluation across the EU.²⁸ Risk assessment is discussed in more depth below.

REACH is complemented by the CLP, the 2008 Regulation for Classification, Labeling and Packaging of Substances and Mixtures.²⁹ This Regulation incorporates the classification criteria and labeling rules agreed at UN level, namely the Globally Harmonised System of Classification and Labeling of Chemicals (GHS). GHS is based on the principle that the same hazards should be described and labeled in the same way all around the world. While REACH and CLP are complementary and, in some ways, interlinked, this thesis is concerned solely with REACH.

Toxic Ignorance: Using and Assessing Chemicals

There are a series of challenges in understanding the risks from chemicals. These challenges impact on and frame the regulatory structures for chemicals control. The overview which follows is thus useful for understanding some of the difficulties with REACH, and its predecessors, that are explored throughout this Chapter and those which follow.

Every substance has the potential to harm us, be it natural or synthetic. Building on observations by Paracelsus in the 16th century, Durodie comments that

“As every toxicologist knows, all substances produce an effect – it is the dose that makes the poison. The fact that a substance contains a toxin does not make it poisonous: if this was true, all foods, which inevitably contain salt, a known toxin at high doses, would have to be banned.”³⁰

The fundamental difference, according to dominant conceptualisations of harm, is between hazard (the inherent potential harmfulness of the chemical) and risk (how and to what extent a receptor is exposed to the hazard). In terms of hazard, chemicals

²⁸ *ibid*

²⁹ Council Regulation (EC) on classification, labelling and packaging of substances and mixtures [2008] OJ L353/1

³⁰ Bill Durodie, ‘The True Cost of Precautionary Chemicals Regulation’ (2003) 23 Risk Analysis 389

may cause cancer, mutate our genes or be harmful to reproduction.³¹ They can accumulate and persist in the environment to such a degree that the same synthetic chemicals can be found in breast milk and polar bears.³² The extent to which chemicals actually cause harm (i.e. their risk) is more contingent and contested, and rests ultimately on the variability of exposure. In the last fifty years, worldwide production of chemicals has risen from 10 million tonnes p/a to over 400 million tonnes p/a.³³ Cefic, the EU chemicals industry lobbying organisation, estimates that the same number of people work in the chemicals sector in the EU as make up the entire working population of Belgium.³⁴

Outside occupational contexts, interaction with chemical substances is commonplace in almost every aspect of our lives: the clothes we wear, the food we eat, the air we breathe, the products we buy. Despite this, and despite the massive increase in chemicals production over the last five decades, we know very little about their precise uses, circulation and implications, particularly those beyond the short term. Alongside our increasing dependence on chemicals, societal attitudes towards chemicals and the chemicals industry have also changed over time. Gunningham, for example, notes that,

“Over the last 50 years the public image of the chemical industry has changed from that of the miracle provider of scientific products enhancing the wellbeing of the community to that of the demon, capable of destroying the world in the interest of private profit.”³⁵

In the 2013 Eurobarometer on Chemicals, 61% of respondents said they felt that chemicals on the EU market are safer today than they were 10 years ago (although the study does not drill down into why EU citizens feel this nor, indeed, do we know just how unsafe chemicals were perceived as being a decade ago).³⁶ It is precisely these inconsistencies and contradictions, between reliance on the one hand and potential

³¹ Randell C Baselt, *Disposition of Toxic Drugs and Chemicals in Man* (9th edn, Atlas Books 2011)

³² Margot Wallstrom, ‘Beyond REACH’ (European Voice Conference, Brussels, 31 March 2003)

³³ Britta Eklund and Jenny Karlsson, ‘Assessing Chemical Risks: Evaluating Products. Rather than Substances, and the Case of Anti-fouling Paints’ in Johan Eriksson, Michael Gilek and Christina Rudén (eds) *Regulating Chemical Risks* (Springer 2010) 163

³⁴ <<http://www.cefic.org/Facts-and-Figures/>> accessed 10 August 2014

³⁵ Neil Gunningham, ‘Policing Pollution: Regulating the Chemical Industry’ (Report for the Criminology Research Council, Australian Centre for Environmental Law, 1994) 3

³⁶ Commission, ‘Flash Eurobarometer 361: Chemicals’ (Brussels, February 2013)
<http://ec.europa.eu/public_opinion/flash/fl_361_en.pdf> accessed 10 August 2014

detriment on the other, that make chemical regulation a particularly vexing problem and a particularly interesting field of study.

An important part of the scientific enterprise is the development of assessments, investigations, standards of proof, and research methodologies “to produce comparatively objective knowledge that will stand the test of time.”³⁷ Much has been written on risk regulation, science and decision-making and on the sociology of scientific knowledge.³⁸ It is not my intention to replicate that work here. It suffices, however, to say that certainty and objectivity in the production of scientific knowledge are themselves contested. The standard tripos of risk management sees hazards identified, evaluated and ‘risk’ (the likelihood that the hazard will materialise in a given situation) minimised as far as possible. In the context of chemicals, risk assessment is and has been imperfect. As Applegate and Campbell-Mohn put it, “Inferences, extrapolation and assumptions necessarily pervade the...risk assessment process.”³⁹ With regard to chemicals, Hansson and Rudén highlight three key reasons for difficulties with the methods of risk assessment, leaving aside any broader issues of the phenomenon of producing objective data.⁴⁰ First, it is not possible to assess the effects of a substance on all species under all conditions. Second, it is not possible to assess all combinations of exposure routes and endpoints even in a single species. Third, it may be impossible to distinguish even large harmful effects from random variations.⁴¹ Their argument, as opposed to that of Applegate and Campbell-Mohn, is that even if risk assessment was a value neutral deterministic, it would still not be possible to rely upon it for practical reasons in the context of chemicals. By way of example of the problems with risk assessment, Bengtsson comments on how 29 separate working groups have been unable to give conclusive answers as to the

³⁷ Carl F Cranor, *Toxic Torts: Science, Law and the Possibility of Justice* (CUP 2006) 8

³⁸ The following two pieces are useful starting points, with references to the major works in these areas: Giandomenico Majone, ‘Foundations of Risk Regulation: Science, Decision Making, Policy Learning and Institutional Reform’ (2010) 1 *European Journal of Risk Regulation* 5; and Andrew Faulkner, Bettina Lange and Christopher Lawless, ‘Material Worlds: Intersections of Law, Science, Technology, and Society’ (2012) 39(1) *Journal of Law and Society* 1

³⁹ John S Applegate and Celia Campbell-Mohn, ‘Risk Assessment: Science, Law and Policy’ (2000) 14 *Natural Resources and Environment* 219, 221

⁴⁰ Sven Ove Hansson and Christina Rudén, ‘REACH: What Has Been Achieved and What Needs to be Done’ in Johan Eriksson, Michael Gilek and Christina Rudén (eds) *Regulating Chemical Risks* (Springer 2010) 163

⁴¹ They give the example of how a 10% increase in cancer rates (which are generally 10% for a random sample of the population) would be statistically insignificant, but potentially large in number across a population.

carcinogenicity of trichloroethylene, a single substance.⁴² These challenges become ever more acute where, instead of looking at single substances, we are trying to understand synergistic effects (the impact of Chemical A and Chemical B) or the impacts from complex polymers or mixtures.⁴³

The difficulties with testing noted in brief above mean that we have limited information on chemical hazards or on chemical risks. Here, the European Environment Agency argues that “‘no evidence’ does not necessarily mean ‘no effects.’”⁴⁴ At the same time, because we know that some of the impacts from chemicals are significant, irreversible and have long gestation periods, waiting for ‘hard’ correlative data may well be the wrong approach to regulating chemicals. There is, then, an inescapable temporal element to chemical harms. The premise behind much of modern chemicals control, including much of REACH, is that risks can be managed via hazard characterisation and then risk assessment. However, Majone observes that while uncertainty is accepted as being pervasive in risk regulation, what is less well understood is that in many cases scientific uncertainty cannot be reduced significantly. He gives an example from Weinberg:

“...in order to determine by direct experimentation at the 95% confidence level whether a level of X ray radiation of 150 millirems would increase spontaneous mutation in mice by half of one percent, about 8 billion mice would be required.”⁴⁵

This is an area of law bound by practical limitations, but the issue is not solely one of ‘8 billion mice’. The problem is more systemic and pathological, owing to the relatively short history of chemicals control in the EU and the nature and form of those controls. The following section discusses three general themes seen in the last five decades of chemicals regulation. The section which follows then looks at the particular history of REACH.

⁴² Bengtsson (n 12) 206

⁴³ European Environment Agency, ‘Chemicals in the European Environment: Low Doses, High Stakes’ (1998)

⁴⁴ *ibid*, 5

⁴⁵ Majone (n 38) 5

Revolutionary it may be, but REACH is not a panacea for previous legislative ills. The idea that REACH provides an all-round solution is problematic, not least because it implies a clean break with the legislation before it. REACH is not entirely separate or different from its legislative predecessors. Rather, it is connected to and bears a contingent relationship with the past five decades of chemicals policies and practices. Looking to that past is useful because it explains why REACH is the way it is. As the European Commission has noted in a review of the former regulatory regimes, EU chemicals law has struggled with the “burden of the past.”⁴⁶

General Themes in Five decades of EU Chemicals Regulation

In other work (with Elen Stokes), I have argued that three general themes can be seen in the last five decades of EU chemicals control.⁴⁷ These are: (i) the centralisation of regulatory responsibility; (ii) EU colonisation and extended control, in the form of increasingly technical and specialised regulatory measures; and (iii) the standardisation of practice, particularly in areas of information provision.

In the context of centralisation, early EU chemical law tells a familiar story about patterns of governance in the process of European integration. In order to achieve its goal of market harmonisation, the EU undertook to reduce the differences among the national laws of Member States. Co-ordinating the economies of the (then six) Member States required (among other things) the assimilation of national laws.⁴⁸ In the chemicals sector, this was brought about by a series of ‘approximation of laws’ activities. Given that national rules on chemicals were identified as having a “direct incidence” on the common market, chemical law and policy (to the extent that it had intra-Community trade implications) became a policy matter for EU institutions not Member States.⁴⁹ Thus from 1967 onwards we saw responsibility for chemicals control flowing up from Member States to the EU. This then changed with REACH, which is said to shift the ‘burden of proof’ onto the private sector.

⁴⁶ Commission, ‘Report on the Operation of Directive 67/548/EEC, Directive 88/379/EEC, Regulation (EEC) 793/93, Directive 76/769/EC’ SEC (1998) final, 2

⁴⁷ Stokes and Vaughan (n 1)

⁴⁸ Belgium, France, Germany, Italy, Luxembourg, The Netherlands

⁴⁹ Treaty Establishing the European Economic Community [1957], art 100

Early on, the central organisation of legislative and bureaucratic tasks provided crucial momentum for the colonisation and control of chemical policy by the EU. This process was gradual, however. Whereas the marketing and use of chemicals were targeted in the very early days of EU policymaking, the actual development and production of chemicals remained entirely free of EU regulation in the 1970s and 80s.⁵⁰ Initially, measures tended to focus on the impact of chemicals on a narrow section of society (industrial workers) but their application was limited to the post-production stages of a chemical's lifecycle. Over time, the scope of chemical regulation broadened to encompass the protection of the environment and public health generally, and its gaze has since turned upstream to research and development activities in the laboratory and downstream to the end-of-lifecycle stage and disposal. However, notwithstanding the EU's colonisation of environmental policy areas previously left to Member States, the simultaneous disaggregation of EU chemical law into sector and media-specific provisions has meant that it has tended to lack a coherent approach. The more sophisticated and widespread EU chemicals regulation became, the more it emerged as a highly compartmentalised collection of rules, having developed in an increasingly sectoral and specialised manner. As Brickman et al comment, "Prior to the 1970s, government regulation of chemical substances was limited to food additives, pesticides and drugs, with some attention given to workplace exposures and to plant siting and construction."⁵¹ With REACH, we see an attempt to regulate a much wider spread of chemicals.

In conjunction with the gradually expanding remit and ambition of EU chemicals law, there has been a move towards increased standardisation. This has manifested in several ways. Substantively, it has been borne out by an increase in the number of legislative measures requiring information provision. Information is, of course, the great market leveler: it increases competition and reduces variety of practice across the Community.⁵² As discussed above, it has always been a basic tenet of chemical regulation that information on the nature, application and impact of chemical

⁵⁰ Marc Pallemarts, 'EC Chemicals Legislation: A Horizontal Perspective' in Richard Macrory (ed) *Reflections on 30 Years of EU Environmental Law* (Europa Law Publishing 2005)

⁵¹ Ronald Brickman, *Controlling Chemicals: The Politics of Regulation in Europe and the United States* (Cornell University Press 1985) 220

⁵² Council Directive (EC) 98/34 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, [1998] OJ L 204/37, Recital 7

substances is limited, at best. Early efforts to dispel the many uncertainties surrounding the link between exposure to chemicals and potential harm to health and/or environmental harm entailed the imposition of pre-market notification requirements. As is shown below, the lack of information of chemicals was one of the key reasons for the introduction of REACH.

The Road to REACH

Prior to REACH, the (then) Community's general chemical regulatory framework consisted of: (i) Directive 67/548/EEC on classification, packaging and labeling (which was the first EU legislative measure on chemicals);⁵³ (ii) a 1976 Directive which sought to restrict the marketing and use of chemical substances;⁵⁴ (iii) a 1993 Regulation on the evaluation and control of 'existing' chemical substances (which required data to be transmitted to the State for evaluation);⁵⁵ and (iv) a 1999 Directive on the classification, packaging and labeling of dangerous preparations.⁵⁶ Under the pre-REACH regimes, how a substance was regulated depended on the date that it was placed on the market. If it was placed on the market before 1981, it was labeled, for the purposes of regulation, as an 'existing' chemical and legislation did not require any systematic testing of its intrinsic properties. If it was placed on the market in or after 1981, it was a 'new' chemical and testing was required. In 2001, of the c.106,000 chemicals on the EU market, less than 1% had been tested and assessed by the relevant EU Member States' competent authorities. In large part, this was said to be the result of asymmetries between the State (as assessor of chemical risks) and the chemicals industry. The Royal Commission on Environmental Pollution said that the regulatory sphere for chemicals pre-REACH was "fragmented and differentiated."⁵⁷ There was wide dissatisfaction with progress made under these regimes and a realisation that change was needed.

⁵³ Council Directive (EEC) 67/548 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances [1967] OJ L 196/1

⁵⁴ Council Directive (EEC) 76/769 on the restrictions of marketing and use of chemical substances. [1976] OJ L 262

⁵⁵ Council Regulation (EEC) 793/93 on the evaluation and control of existing chemical substances [1993] OJ L 84

⁵⁶ Council Directive (EC) 1999/45 on classification, packaging and labeling of dangerous preparations [1999] OJ L 200

⁵⁷ RCEP, 'Chemicals in the Environment' (Royal Commission on Environmental Pollution, 24th Report, 2003) 162

Following an informal meeting of EU environmental ministers in Chester in April 1998, the EU Commission was charged with a review of the then current chemicals legislation. Their report, some seven months later, highlighted,

“the need to use the current [legal] instruments more efficiently and implement as well as enforce them more rigorously and consistently, the need to streamline the instruments and develop them in order to take account of new emerging problems”.

Informed by a stakeholder meeting in February 1999, the Council requested that the European Commission develop a new strategy for more effective chemicals management and emphasised, “the need to work on the development of an integrated and coherent strategy for the future chemicals policy.”⁵⁸

In February 2001, the Commission published a White Paper (“Strategy for a Future Chemicals Policy”), which detailed a radical overhaul of existing policy, comprising of comprehensive risk assessment testing of all chemical substances produced or imported in quantities greater than one tonne per year and a new ‘burden of proof’ such that chemical manufacturers and importers (and not Member States, as had previously been the case) would be the ones obliged to undertake and pay for the relevant testing and registrations.⁵⁹ As for the basis of this new policy, the White Paper cited two main reasons:

- (i) “The incidence of some diseases, e.g. testicular cancer in young men and allergies, has increased significantly over the last decades”; and
- (ii) “There is a general lack of knowledge about the properties and uses of existing substances.”⁶⁰

It is interesting that the Commission cites the increased incidence of certain diseases when, as discussed earlier in this Chapter, there are real challenges in understanding the impacts from chemicals. This argument is also questionable as REACH is

⁵⁸ Council, ‘Community Policy for Chemical Products – Council Conclusions’ (2194th Council meeting, Luxembourg 24/25 June 1999)

⁵⁹ Commission (n 2)

⁶⁰ *ibid*

concerned solely with understanding the intrinsic properties of single substances and does not consider synergistic effects or impacts from mixtures of chemicals (with the latter arguably more likely, in the real world, to impact on human health and the environment).

The EU's new policy on chemical risk management was *set* as of 13 February 2001 when the White Paper was published. As Rogers (one of the policy advisors at the Commission responsible for the new chemicals strategy) comments, "White papers are *statements of policy* that are presented by the European Commission to the European Parliament, the European Council and other bodies and that may well be followed by legislative proposals."⁶¹ Given this, presenting the new chemicals policy as a White Paper (and not, for example, as Green Paper) was significant. The policy aims had already been set by the Commission in the 35 months following the Council meeting in Chester; what was left was debate on their form and method of implementation (that is, the negotiation and drafting of REACH).

From Policy to Legislation

From the White Paper, the road to REACH was long and tortuous. For an in-depth analysis, the guide produced by Inger Schorling, MEP for the Greens/European Free Alliance, is particularly instructive.⁶² Over 4000 amendments to the initial draft of REACH were tabled, discussed and voted on during the first reading in the EU Parliament.⁶³ 41 separate regulatory impact assessments were prepared by lobbying groups, Member States, other countries and regions and NGOs.⁶⁴ This may not be surprising as, as Heyvaert notes, "The European Parliament identified REACH as the single most important dossier ever to be discussed within its walls".⁶⁵ REACH was a radical overhaul of previous chemicals controls and would require much greater

⁶¹ Michael D Rogers, 'The European Commission's White Paper "Strategy for a Future Chemicals Policy": A Review' (2003) 23 Risk Analysis 381, 381 [emphasis as in the original]

⁶² Inger Schorling, 'REACH – The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why?' (Brussels, April 2004) – see: <<http://assets.panda.org/downloads/theonlyplanetguide.pdf>> accessed 10 August 2014

⁶³ See: <<http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?id=23795>> accessed 10 August 2014

⁶⁴ Ineke Gubbels van Hal and Jacques Pelkmans, 'Is REACH going well?' (2009) 198 CEPS Policy Brief 1

⁶⁵ Veerle Heyvaert, 'Globalizing regulation: reaching beyond the borders of chemical safety' (2009) 36(1) Journal of Law and Society 110, 113

involvement in risk assessment by the chemical industry and other users of chemicals. It was highly controversial. Between the publication of the White Paper in February 2001 and December 2006, when the text of REACH was finally agreed, there were five separate stakeholder consultations or conferences, three pilot studies and eight official technical reports.⁶⁶ A more detailed timetable of the road to REACH appears as Appendix 1 to this thesis.

The two key pilot studies prior to the adoption of REACH were: ‘SPORT’, which looked at “strategic partnerships for chemical substance testing” (and simulated the element of REACH which requires the registration of chemical testing data); and ‘PRODUCE’, which looked at the practical impacts of REACH on downstream users (for example, the car manufacturer who uses the specialty chemical made by a company subject to REACH).⁶⁷ At the same time, there was also the SHERPER pilot, which looked into identifying the best strategies for establishing national REACH helpdesks on the basis of the needs of small and medium enterprises.⁶⁸ As the text of REACH was being negotiated the Commission undertook a series of REACH implementation projects (or ‘RIPs’). The Commission details that these projects foresaw, “the development of guidance documents and IT-tools for the European Chemicals Agency, for industry and the authorities of the Member States”.⁶⁹ This in-tandem development of the Regulation (from the Commission via the Parliament and the Council) and its accompanying guidance (via other routes) is particularly interesting and is discussed further in Chapter 4. The following section sets out the methodological approach taken for this thesis.

Thesis Methodology

Background

⁶⁶ See: <http://ec.europa.eu/environment/chemicals/reach/background/i_a_en.htm> accessed 10 August 2014

⁶⁷ See: <http://ec.europa.eu/environment/chemicals/reach/preparing/strategic_partners_en.htm> accessed 10 August 2014

⁶⁸ See: <http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/helpdesk/sherper-report_en.htm> accessed 10 August 2014

⁶⁹ See: <<http://ec.europa.eu/environment/chemicals/reach/preparing/>> accessed 10 August 2014

After my law degree, I qualified as a solicitor and worked in the City, first for Freshfields Bruckhaus Derringer and then for Latham & Watkins. In both firms, I was an environmental lawyer. My clients at Latham were predominantly based in the US and in moving to that firm I found my role became more one of translating and applying EU environmental laws. At Freshfields, I had largely worked as a 'corporate support lawyer', providing advice on the analysis and transfer of environmental risks pertaining to corporate finance deals. At Latham, I was brought within the fold of the global Environmental, Land and Resources practice and introduced to partners, in the US, Belgium and Germany with particular expertise in EU and US chemicals regulation. I also joined the American Chamber of Commerce in Brussels as a Latham representative and was a part of the Brussels chapter of TechAmerica, the industry organisation for the American electronics sector. It was in this latter role that I came to better understand REACH. By 2006, when I moved to Latham, REACH was very much on the horizon and our clients were beginning their preparations for the Regulation coming into force. We initially advised them on compliance strategies, on the setting of the mandatory manufacturer groupings (SIEFs) required under the legislation and on how best they should interact with ECHA.

The complexity of REACH daunted me. It even daunted Latham's partners in the US, some of whom had decades of experience on chemicals regulation, including as former employees of the US Environmental Protection Agency. I often felt that I never really had a good sense of both the big, overarching framework of the Regulation and the detail of what the individual elements required. Frequently we would be asked very specific questions about very small parts of the legislation. Our clients were equally confused by the vastness of REACH but, nevertheless, had to manage compliance. Two things struck me about this. The first was the way in which ECHA provided guidance. For the two to three years post the introduction of REACH (2007 onwards), the Agency seemed to be playing catch up and seemed unable to cope with the uncertainty and complexity that the operation of the Regulation created. In many instances, the Agency asked industry to draft guidance which ECHA would then offer to promulgate as good practice. Certainly, the current guidance is more sophisticated than the original versions, although this might not be immediately apparent, as ECHA does not make public the previous iterations of the guidance it issues. The second striking matter was the heavy reliance by clients (many of whom

were billion dollar multinationals with large in-house legal and toxicology teams) on industry associations for guidance and advice.

When I left practice, I wanted to research something for my PhD that was large and relatively unexplored and dense.⁷⁰ REACH seemed the obvious choice to me, though many (including many environmental law academics) find the legislation (and chemicals regulation more generally) both difficult and dull. REACH is certainly a behemoth and there have been many times when I have struggled to understand the complexity of the Regulation and also to understand why something had been done in a particular way. But I have also come to value the importance of exposition in legal scholarship, in being able to offer up a vision of the complexities of regulation in specific fields.

A wealth of PhDs could be undertaken on REACH. Instead of depth on one aspect of REACH or one issue, I decided that I wanted to provide a rigorous and robust review of the entire Regulation. Certainly, this is something I would have valued while in practice and it is something that is missing in the existing writing on REACH (largely, I imagine, for reasons of time and space). I also found the interplay between ‘law’ and ‘guidance’ fascinating. In practice, we had treated regulatory guidance as authoritative and spent a good deal of our time ‘lawyering’ ways around the specific wording of specific guidance documents (on REACH and other EU environmental laws). It was only on leaving practice that I had the time and space to reflect on the role of guidance and what its use and promulgation meant (and means) for matters like transparency, accountability, redress etc, which are explored in this thesis.

Research Questions

As set out earlier in this Chapter, this thesis has two overarching objectives. The first is to provide an exposition of REACH. The second aim of this thesis is to explore REACH using literature on hard and soft law and, in particular, writing which looks at post legislative norm elaboration via the use of guidance. To those ends, this thesis is underpinned by the following research questions:

⁷⁰ Looking back, this may have been a mistake.

1. What does REACH say and how does the Regulation work?
2. What academic writing is there on REACH and what does this writing tell us about the Regulation and also about the scholarly interests of the authors?
3. What guidance is there on REACH produced by ECHA and how does this guidance shape and channel the operation of the Regulation?
4. What functions does the guidance serve? Are there instances where the guidance does more than simply explain the text of REACH? Are there instances where the guidance requires action that is not also set out in the text of the Regulation?
5. What other guidance is there on REACH (for example, by trade associations) and how does this guidance shape and channel the operation of the Regulation?
6. What writing is there on ‘hard law’ and ‘soft law’ and, in particular, on post legislative norm elaboration in the EU?
7. What does the amount and nature of the guidance on REACH mean for current understandings of the ‘hard law’/‘soft law’ divide generally and, more specifically, for post legislative norm elaboration in the EU?

Research Design

This thesis is legal doctrinal research inasmuch as it is, “research into the law and legal concepts” and does not draw upon empirical data.⁷¹ Referring to a ‘Statement on the Nature of Legal Research’ by the Council of Australian Law Deans, Hutchinson and Duncan suggest that,

⁷¹ Terry Hutchinson and Nigel Duncan, ‘Defining and Describing What We Do: Doctrinal Legal Research’ (2012) 17(1) Deakin Law Review 83

“To a large extent, it is the doctrinal aspect of law that makes legal research distinctive and provides an often under-recognised parallel to ‘discovery’ in the physical sciences. Doctrinal research, at its best, involves rigorous analysis and creative synthesis, the making of connections between seemingly disparate doctrinal strands, and the challenge of extracting general principles from an inchoate mass of primary materials.”⁷²

More specifically, this thesis uses content analysis to understand REACH and how the Regulation is framed and presented by ECHA (and others) via guidance. Krippendorff states that, “content analysis is a research technique used for making replicable and valid inferences from texts (or other meaningful matter) to the contexts of their use.”⁷³ Bryman takes a narrower view and writes that, with content analysis, there is, “an emphasis on allowing categories to emerge out of data and on recognising the significance for understanding the meaning of the context in which an item being analysed (and the categories derived from it) appeared.” However, Krippendorff denies any absolute and necessary connection between content analysis and objectivity or quantification.⁷⁴

Doctrinal legal research is said to have two steps: location of the sources of law and then, “interpreting and analysing the text.”⁷⁵ Both steps are present in this thesis and I would argue that second can amount to a form of content analysis. This, however, is not accepted by Hutchinson and Duncan.⁷⁶ Instead, they argue that doctrinal analysis and content analysis differ in that the latter, “is the process of quantifying the use of words and then examining the language, and not simply what is being said or the meaning of the words in the first instance.”⁷⁷ They argue that content analysis is a way of deconstructing text rather than reading and synthesising meaning from the text.⁷⁸ It is suggested that this is based on a rather narrow understanding of content analysis (more in keeping with Bryman than Krippendorff) and that content analysis

⁷² *ibid*, 105

⁷³ Kristopher Krippendorff, *Content Analysis: An Introduction to its Methodology* (Sage Publications 2013) 24

⁷⁴ *ibid*, Chapter 2

⁷⁵ Hutchinson and Duncan (n 71), 110

⁷⁶ *ibid*

⁷⁷ Hutchinson and Duncan (n 71), 118

⁷⁸ *ibid*

can both read/synthesize text as well as deconstruct it. It is also submitted that much (but by no means all) doctrinal analysis is, in fact, a form of content analysis.

As an approach, content analysis takes a variety of forms. Some content analysis (the school of thought on which Hutchinson and Duncan draw) seeks to take a qualitative approach (e.g. what words are used and what they mean) and turn that into a more quantitative process, through detailed coding and analysis.⁷⁹ That is not the approach taken in this thesis. Instead, the text of REACH was first read in its entirety to gain a sense of how the Regulation worked as a whole. The legislation was then read a second time, which led to the creation of Chapter 3, the general overview of REACH. The next step was to look at all of the available ECHA guidance. I say ‘look at’ because some of the guidance is wholly technical and I did not read every single word of every single guidance document. But I did read every section of every guidance document that was not purely technical. I then compared the guidance with the text of REACH and asked myself: what is the function of this guidance? does it add anything to REACH? if so, how? I also looked at the various guidance produced by the Health and Safety Executive (as the relevant REACH ‘competent authority’ for the UK) and by a number of trade associations. In terms of approach, this thesis has been part inductive and part deductive. My original hypothesis was that guidance produced by ECHA *would* do more than simply explain the text of REACH (simply because of its volume). However, my understanding of exactly *what* that guidance would do only became clear from having read the guidance and compared it to the Regulation.

The sheer amount of text has at times been overwhelming. However, the very complexity of REACH and the large supportive framework of accompanying guidance make this aspect of chemicals regulation a suitable subject for detailed, rigorous analysis. As McCrudden has observed, “if legal academic work shows anything, it shows that an applicable legal norm on anything but the most banal question is likely to be complex, nuanced and contested.”⁸⁰ This has been seen as the overriding duty of the legal scholar. Indeed, Oliver Wendell Holmes Jr notes that, “The business of the jurist is to make known the content of the law; that is, to work

⁷⁹ For a review, see: Hsiu-Fang Hsieh and Sarah E. Shannon, ‘Three Approaches to Qualitative Content Analysis’ (2005) 15 *Qualitative Health Research* 1277

⁸⁰ Christopher McCrudden, ‘Legal Research and the Social Sciences’ [2006] *Law Quarterly Review* 632, 648

upon it from within, or logically, arranging and distributing it, in order, from its *stemmum genus* to its infima species, so far as practicable”.⁸¹ My hope, therefore, with this thesis is to have made known the content of REACH and its guidance.

Thesis Structure

Chapter 2 of this thesis surveys the literature on new governance and on hard and soft law. It focuses in particular on the small subset of work which has looked at the role of post legislative norm elaboration via guidance. As noted above, REACH is complex and complicated. 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.

The following five Chapters each then review a substantive element of REACH. 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 through 8 each detail and critique the role of guidance in relation to the operation of REACH. Chapter 9 frames the contributions of this thesis within wider scholarship on new governance and explores, in detail, the differentiation within soft law that is seen with REACH. Chapter 10 brings together some overarching themes from this thesis in a short conclusion.

⁸¹ Oliver Wendell Holmes Jr, ‘The Common Law Project Gutenberg’ (December 2000), 219 – see: <<http://www.gutenberg.org/dirs/etext00/cmnlw10.txt>> accessed 10 August 2014

CHAPTER 2

LITERATURE REVIEW – NEW GOVERNANCE, HARD LAW, SOFT LAW AND GUIDANCE

Overview

This thesis is concerned with post legislative norm elaboration via the use of guidance. Writing in this particular area is a subset of the literature on hard and soft law, which itself forms part of the much broader field of new governance. This literature review is primarily concerned with scholarship on hard and soft law in the EU, but begins by scene setting with a brief overview of new governance.

Trubek and Trubek describe new governance as a, “wide range of processes which have developed and are designed to carry out public objectives using methods that differ in one way or another from classic forms of law.”¹ We are concerned then with a plurality of non-hierarchical modes of political steering in which public policymakers seek to maintain social and economic order. They write that the co-existence of new governance approaches and more classic methods of regulation (i.e. binding norms via legislation) is seen in, “numerous possible configurations and relationships”.² ‘New governance’ is not an homogenous approach. However, it is possible to set out some overarching themes. Here, De Burca and Scott argue that the common features of new governance approaches, “involve a shift in emphasis away from command and control in favour of ‘regulatory’ approaches which are less rigid, less prescriptive, less committed to uniform outcomes and less hierarchical in nature.”³ Armstrong writes that the EU is a “striking illustration” of a phenomenon which sees, “pluralisation and differentiation in the techniques, tools and methods

¹ David M Trubek and Louise G Trubek, ‘The Coexistence of New Governance and Legal Regulation: Complementarity or Rivalry?’ (Paper, Annual Meeting of the Research Committee on the Sociology of Law, Paris, July 2005) 1

² *ibid*

³ Grainne de Burca and Joanne Scott, ‘Governance, Law and Constitutionalism’ in Grainne de Burca and Joanne Scott (eds) *Law and New Governance in the EU and the US* (Hart Publishing 2006) 2

deployed by public and private actors in the search for more legitimate and/or more effective means of securing economic and social governance.”⁴

All of the authors referred to above argue that soft law falls within the realms of new governance. De Burca and Scott comment that, “A further characteristic often present in new governance processes is the voluntary or non-binding nature of the norms...which is sometimes described in terms of “soft law”.”⁵ While this broad reference point is useful, defining the nature and limits of soft law is more difficult.

Soft Law Definitions

As Shelton has observed, “Soft law comes in an almost infinite variety.”⁶ Starting in the 1970s much of the writing on hard law/soft law comes from literature in law and political science on international relations and public international law⁷. In this area, defining ‘law’ (and, as a corollary, its hard and soft forms) is difficult and soft law in this context is largely (but not exclusively) premised on informality and voluntarism.⁸ While this body of literature is interesting, there is a good amount of writing on hard and soft law issues specific to the EU. It is this subset of the soft law literature on which this thesis primarily draws. As Borchardt and Wellens note in their leading 1989 article on soft law in the (then) EC,

“[A] number of aspects of the international legal problems involved will either not arise within Community law, or will present themselves in a different form or level of intensity, because of its own characteristics.”⁹

⁴ Kenneth Armstrong, ‘New Governance and the EU: An Empirical and Conceptual Critique’ (Queen Mary School of Law Legal Studies Research Paper No. 135/2013, 2013).

<http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2244762> accessed 10 August 2014

⁵ de Burca and Scott (n 3) 3

⁶ Dinah L Shelton, ‘Soft Law’ in David Armstrong (ed) *Handbook of International Law* (Routledge 2008) 3

⁷ By way of a starting point into this literature, see the special issue of *International Organisation* (2000(3)).

⁸ John J. Kirton and Michael J. Trebilcock, ‘Hard Choices, Soft Law: Voluntary Standards in Global Trade’ in John J. Kirton and Michael J. Trebilcock (eds), *Hard Choices, Soft Law: Voluntary Standards in Global Trade, Environment and Social Governance* (Ashgate 2004) 9

⁹ Gustaaf M Borchardt and Karel Wellens, ‘Soft Law in European Community Law’ (1989) 14(5) *E.L. Rev.* 267, 267

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.”¹⁰ Lee writes that soft law instruments are “likely to have” the endorsement of a community institution, but lack the formality required of the Treaty as regards law making.¹¹ 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.”¹²

It is worth noting that these are but two of a large number of definitions.¹³ The field is further amorphous as some authors use different terms: ‘self-regulation’ (often in the context of private codes of conduct);¹⁴ ‘quasi legislation’;¹⁵ or ‘informal instruments.’¹⁶

Abbott and Snidal argue that soft law operates along one or more three dimensions: “obligation, precision and delegation”.¹⁷ The notion of obligation (or legal bindingness) is seen time and time again in the literature.¹⁸ However, one should not be blinded by binding. Here, Jacobsson writes that one of the interesting sociological questions is how soft law instruments,

“can gradually become politically, socially and morally binding for the actors involved. How can external expectations be perceived as valid

¹⁰ Francis Snyder, ‘The Effectiveness of EC Law’ (1993) 56(1) MLR 19, 32

¹¹ Robert G Lee, ‘The Food Strategy for Wales; A Soft Law Instrument’ in Patrick Bishop and Mark Stallworthy (eds) *Environmental Law and Policy in Wales: Responding to Local and Global Challenges*, (University of Wales Press 2013) 1

¹² Linda Senden, *Soft Law in European Community Law* (Hart 2004) 3

¹³ See Senden (ibid) for a review and critique of these

¹⁴ Maria Goncalves and Maria Gameiro, ‘Hard Law, Soft Law and Self Regulation: Seeking Better Governance for Science and Technology in the EU’ (Dinâmia Working Paper 2011/18) 6

¹⁵ Gabriele Ganz, *Quasi Legislation: Recent Developments in Secondary Legislation* (Sweet & Maxwell 1987)

¹⁶ Anthony Aust, ‘The Theory and Practice of Informal International Instruments’ (1986) 35(4) *International and Comparative Law Quarterly* 787

¹⁷ Kenneth Abbott and Duncan Snidal, ‘Hard and Soft Law in International Governance’ (2000) 54(3) *International Organisation* 421, 438

¹⁸ Senden (n 12) 112

norms and/or gradually be internalised and perceived as the ‘reasonable’ way to act?”¹⁹

In a similar vein, Borchardt and Wellens detail that “soft law does create an expectation that conduct of states, international organisations and the individual will be in conformity with the non-binding rules of conduct.”²⁰ Jacobsson comments that bindingness in the context of soft law is not absolute and that, “one can imagine courses of action where actors conform and adapt in some respects and preserve their interests and initial positions – refusing conformity – in others.”²¹ As Senden observes, “the distinction binding/non-binding is too black-and-white, too simple to do justice to the phenomenon of soft law and its possible legal effect”.²² Importantly, the European Court of Justice has recognised that lack of bindingness is not synonymous with lack of legal effect.²³

In his wide ranging review of new governance scholarship, Armstrong argues, in the context of soft law and the issue of bindingness, that “what seems to matter more to new governance scholars are the mechanisms and processes by which norms – binding or not – are elaborated and their performance reviewed in the context of their application.”²⁴ Thus, context seems an important determinant for different authors of what does and does not count as soft law.²⁵ As Borchardt and Wellens elaborate,

“the way in which soft law is being defined in legal doctrine is directly determined by the function intentionally assigned to it, the way in which the concept is being or can be used and also by the phenomena which one can or wants to distinguish or identify as the forms in which soft law presents itself.”²⁶

¹⁹ Kerstin Jacobsson, ‘Soft regulation and the subtle transformation of states: the case of EU employment policy’ (2004) 14(4) *Journal of European Social Policy* 355, 359

²⁰ Borchardt and Wellens (n 9) 312

²¹ Jacobsson (n 19) 359

²² Senden (n 12) 110

²³ Case C-322/88 *Grimaldi* [1989] ECR I-4407

²⁴ Armstrong (n 4) 27

²⁵ See, for example, the different definitions of soft law used by different authors from different disciplinary backgrounds in: Ulrika Morth (ed), *Soft Law in Governance and Regulation: an Interdisciplinary Analysis* (Edward Elgar Publishing 2004)

²⁶ Borchardt and Wellens (n 9) 270

The understandings of soft law in the literature also seem contingent on how authors view the underlying purpose of soft law. Surveying the hard law/soft law literature on the EU's open method of co-ordination and on EU fiscal policies, Trubek et al highlight two different accounts: the rationalist account which sees soft law as a way for States to defer decision making and avoid hard choices; and the constructivist account which sees soft law as facilitating the hard decisions that the rationalists think are being deferred.²⁷ They argue that, "since reality probably reflects a mix of these two motives and effects, it seems clear that we need a synthetic approach to soft law that would integrate elements of these two perspectives."²⁸ I would agree.

Trubek and Trubek note that soft law may either be complementary to or have a rivalry with classic legal regulation.²⁹ In many situations, hard law and soft law are not mutually exclusive. In this context, hybridity connotes the idea of hard and soft policy measures in the same field, either as a result of a conscious design effort or because two separate routes (one hard, one soft) pursue the same end goal.³⁰ Trubek et al suggest that ambiguities at the frontiers of the concepts of soft law, self-regulation and hard law point to, "hybrid constellations in which both hard and soft processes operate in the same domain and affect the same actors."³¹ REACH is a classic case of a designed hybrid model in which the Regulation foresaw the need for detailed post legislative elaboration. This is discussed in greater detail in Chapter 4. De Burca and Scott, in a wider review of new governance, detail three possible forms of hybridity: (a) fundamental or baseline hybridity, which sees new governance as complementary to (rather than a replacement of) more traditional forms of law;³² (b) instrumental or developmental hybridity, which sees new governance as an instrumental means of developing traditional law;³³ and (c) default hybridity, in which traditional law becomes a 'default penalty' applicable where there is failure to conform to the demands of new governance.³⁴ They suggest that the clearest EU

²⁷ David M Trubek, Patrick Cottrell and Mar Nance, 'Soft Law, Hard Law and European Integration: Toward a Theory of Hybridity' (University of Wisconsin Legal Studies Research Paper No. 1002, 2005) 30-31

²⁸ *ibid*

²⁹ Trubek and Trubek (n 1) 5-8

³⁰ Trubek et al (n 27) 33

³¹ Trubek et al (n 27) 3-4

³² de Burca and Scott (n 3) 7

³³ de Burca and Scott (n 3) 8

³⁴ de Burca and Scott (n 3) 9

example of developmental hybridity is seen with Directives that have new governance regimes for their implementation, with the example given of the Water Framework Directive.³⁵ This Directive, and the associated governance work on it, is discussed in more depth below.

What should be clear by now is that, as Senden writes, soft law is a “far from [an] homogenous phenomenon.”³⁶ The purpose in defining ‘soft law’ is often to differentiate it 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.”³⁷ Given the varying and numerous attempts to ascertain the exact nature of ‘soft law’, there seems to be little point in setting out a “non-exhaustive miscellany of descriptions.”³⁸ 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,”³⁹ getting agreement on one definition and one understanding seems highly unlikely. Instead, what may be more productive is to explore and explain why ‘soft law’ has been used in the EU and the limits and challenges of the concept. Senden argues (and I would agree) that the notion of ‘soft law’, “provides a maybe not perfect, but at least reasonably satisfactory umbrella concept.”⁴⁰ For present purposes, ‘soft law’ is used 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.⁴¹ The following section discusses hierarchy and differentiation in EU norms before turning to the benefits and critique of ‘soft law’.

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

³⁵ de Burca and Scott (n 3) 8

³⁶ Senden (n 12) 23

³⁷ Kirton and Trebilcock (n 8) 8

³⁸ Borchardt and Wellens (n 9) 272

³⁹ Gregory Shaffer and Mark A. Pollack, ‘Hard and Soft Law: What Have We Learned?’ (University of Minnesota Law School, Legal Studies Research Paper Series Research Paper No 12-17, 2012) 19

⁴⁰ Senden (n 12) 110

⁴¹ Trubek et al (n 27) 1

alone has competence; those where competence is shared with Member States; and those areas the exclusive domain of the Member States.⁴² 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.⁴³ Directives are binding as to the result to be achieved, but leave the form and means of achievement open to Member States.⁴⁴ 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).⁴⁵ 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.⁴⁶ 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.”⁴⁷ 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’ institutional practice over time.⁴⁸

Kirton and Trebilcock⁴⁹ write that the EU is an institution grounded on hard law. Historically, the EU has worked on the basis of top down, hierarchical, binding norms (Regulations and Directives) as a means of harmonisation: the classic command and control model of regulation operationalised via the Community Method. Over time, however, and as seen in other national and supranational contexts, the variety of

⁴² Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community [2007] OJ 2007 C 306/1

⁴³ Article 288, TFEU (formerly Article 249 TEC)

⁴⁴ *ibid*

⁴⁵ *ibid*

⁴⁶ *ibid*

⁴⁷ Carol Harlow and Richard Rawlings, *Law and Administration* (CUP 2009) 192

⁴⁸ Linda Senden, ‘Soft Post Legislative Rulemaking: A Time for More Stringent Control’ (2013) 19(1) *European Law Journal*, 57, 57. See also: Linda Senden and Ton van den Brink, ‘Checks and Balances of Soft EU Rule Making’ (Report for the European Parliament, March 2012)

⁴⁹ Kirton and Trebilcock (n 8) 347

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.⁵⁰ 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.”⁵¹ The following section discusses the benefits of these ‘non-binding tools’, before considering the limits and critique of soft law.

The Benefits and Limits of Soft Law

Kirton and Trebilcock summarise the benefits of soft law as follows:

“timely action when governments are stalemated; bottom up initiatives that bring additional legitimacy, expertise and other resources for making and enforcing new norms and standards; and an effective means for direct civil society participation in global governance.”⁵²

In the particular context of the EU, Harlow and Rawlings argue that the “exceptional complexity” of law making procedures might make soft law attractive in this area.⁵³ However, while the use of soft law may be attractive and the concept as a topic of study has received increasing attention, this has not always been positive. Indeed, there are a number of scholars who argue that the notion of ‘soft’ law is a contradiction: either law is binding (or hard) or it is not law.⁵⁴ For present purposes, this debate can be avoided. There are instruments out there which do not look like traditional legislative instruments that are designed to be binding on the parties to whom they are addressed, but which nevertheless may cause those parties to act in

⁵⁰ Commission, ‘European Governance’ (White Paper) COM(2001) 428 final, 20

⁵¹ *ibid*

⁵² Kirton and Trebilcock (n 8) 5

⁵³ Harlow and Rawlings (n 47) 192

⁵⁴ See, for example: Prosper Weil, ‘Towards Relative Normativity in International Law?’ (1983) 77(3) *American Journal of International Law* 413; Jan Klabbbers, ‘The Redundancy of Soft Law’ (1996) 65(2) *Nordic Journal of International Law* 167; Jan Klabbbers, ‘The Undesirability of Soft Law’, (1998) 67(4) *Nordic Journal of International Law* 381; Harmut Hillegenberg, ‘A Fresh Look at Soft Law’, (1999) 10(3) *European Journal of International Law* 499

certain ways and so have some kind of effect. Whether or not those instruments are law cannot be wholly ascertained through scholarly rhetoric, but would require (in each instance) review by the courts. Justiciability is discussed in more depth below. In a recent piece, Armstrong has argued that, “scholarship ought to make a more decisive break with the concept of ‘soft law’: a concept that is both over- and under-inclusive in its capacity to capture changes in law and governance.”⁵⁵ This is, it seems, not so much an attack on the phenomenon itself but on the pigeon holing by certain scholars of ‘soft law’ scholarship into a world of its own without reference to broader issues and debates in law and governance.

On a more general (and perhaps important) level, objections to the use of soft law (specifically within the EU) include the lack of clarity, concerns about a race to the bottom in EU social policy, the possibility that soft law is a covert attempt by the EU to enlarge its legislative competence and/or the worry that soft law passes the usual systems of accountability.⁵⁶ Kirton and Trebilcock note that soft law may “lack the legitimacy and strong surveillance and enforcement mechanisms offered by hard law” and may lead to uncertainty “as actors remain unclear about...when governments might intervene to impose a potentially different, mandatory regime”.⁵⁷ Klabbbers has argued that soft law is undesirable as it has the potential to crowd out hard law in regulating behaviors through non-legally binding norms.⁵⁸ These fundamental issues of power, legitimacy and democracy echo throughout the work on and the use of soft law. The challenges of and for soft law are further discussed at the end of this Chapter.

As Trubek et al have observed⁵⁹, the critiques of hard law and soft law tend to be centred on pragmatic issues: in essence, ‘which works best?’, with the critics taking the view that hard law is required to achieve whatever EU objectives are in question. They argue that, because the issue is a pragmatic one, the question is not necessarily one of “hard law versus soft law” as there is also the sphere in which the two

⁵⁵ Armstrong (n 4) 3

⁵⁶ The best starting point for a greater discussion of these (and other) criticisms is: Klabbbers (1998) (n 54)

⁵⁷ Kirton and M J Trebilcock (n 8) 6

⁵⁸ Klabbbers (1998) (n 54)

⁵⁹ Trubek et al (n 27) 3

processes interact creating “hybrid” forms of governance.⁶⁰ However, the examples that Trubek et al give (EU fiscal policy and EU employment policy) both concern spheres where the soft law (guidelines) co-exist and overlap with hard instruments (i.e. separate but together). My focus is primarily on the use of soft law to elaborate on hard law through post legislative guidance. This is discussed below.

The European Parliament has cautioned against the dangers of relying too greatly on soft law, particularly when authority for the design of particular soft law instruments is delegated to bodies lacking democratic control.⁶¹ In its September 2007 Resolution on the use of soft law instruments, the Parliament details concerns that soft law does not “provide full judicial protection,”⁶² brings “confusion and insecurity”,⁶³ and generates a “public perception of “superbureaucracy” with no democratic legitimacy.”⁶⁴ There is perhaps some irony in that, should the Resolution have practical effects, it too may be considered an instrument of soft law.

Surveying the Field: Scholarship on EU Hard Law/Soft Law

In 2004, Senden wrote that,

“The use of soft law in EC law is both fashionable and problematic. Fashionable in view of the increasing flow of Community soft law acts, such as recommendations, communications, notices, guide- lines, codes of conduct, declarations. Problematic in that it is *un droit au statut incertain*... which raises the question to what extent one can consider these acts to form part of EC law at all.”⁶⁵

Almost a decade later and the appetite of the EU for soft law measures (whether stand alone or in hybrid forms with harder instruments) has not decreased, nor have scholars disengaged from work on the concept, although it is fair to say that the

⁶⁰ *ibid*

⁶¹ European Parliament, ‘Resolution on institutional and legal implications of the use of “soft law” instruments’ (A6-0259/2007, 4 September 2007)

⁶² *ibid*, para D

⁶³ European Parliament (n 61), para N

⁶⁴ European Parliament (n 61), para Y

⁶⁵ Senden (n 12) 3

majority of the literature remains within scholarship on international law and international relations.

As Senden observes, the notion of soft law has been applied to a number of settings in the EU since the 1980s.⁶⁶ In the last decade alone, we have seen discussions of soft law in relation to EU instruments on state aid⁶⁷, EU fiscal governance⁶⁸, the open method of co-ordination⁶⁹, EU employment policy⁷⁰, EU integration and accession⁷¹, EU competition law⁷², EU governance of retailing⁷³, control of new and emerging technologies within the EU⁷⁴ and EU tax law.⁷⁵

Senden's seminal work on soft law in the EC explored the differentiation of soft law from hard law and looked at how soft law instruments and their use fit in to the Community legal order. Her main focus was to explore the situations in which soft law could provide a satisfactory alternative to legislation in the EC. She identifies two streams of writing at EC level on soft law: that which looks at instruments that resemble those found in international law (conclusions, declarations, recommendations, resolutions and the like, adopted by notably the Council, Representatives of the Governments of the Member States meeting in Council or by the Member States themselves) and that which reviews soft law instruments generated by the Commission.⁷⁶ Her monograph divides EC soft law instruments into two types: the first category is designated as preparatory and informative instruments; the

⁶⁶ Senden (n 12) 109

⁶⁷ Michelle Cini, 'The soft law approach: Commission rule-making in the EU's state aid regime' (2001) 8(2) *Journal of European Public Policy* 192; and Michael Blauburger, 'Of 'good' and 'bad' subsidies: European state aid control through soft and hard law' (2009) 32(4) *West European Politics* 719

⁶⁸ Waltraud Schelkle, 'EU fiscal governance: hard law in the shadow of soft law' (2006) 13 *Colum. J. Eur. L.* 705

⁶⁹ 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); Kenneth Armstrong and Claire Kilpatrick, 'Law, governance, or new governance-the changing open method of coordination' (2006) 13 *Colum. J. Eur. L.* 649

⁷⁰ Jacobsson (n 19)

⁷¹ Emer O'Hagan, 'Too soft to handle? A reflection on soft law in Europe and accession states' (2004) 26(4) *Journal of European Integration* 379

⁷² Oana A Stefan, 'European Competition Soft Law in European Courts: A Matter of Hard Principles?' (2008) 14(6) *European Law Journal* 753

⁷³ 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)

⁷⁴ Goncalves and Gameiro (n 14)

⁷⁵ Hans Gribnau, 'Soft Law and Taxation: EU and International Aspects' (2008) 2(2) *Legisprudence* 67

⁷⁶ Senden (n 12) 114-115

second category comprises the interpretative and decisional instruments.⁷⁷ While this clear delineation may have been true in 2004, this thesis shows that the lines are more blurred with REACH. In her later work, with van den Brink, the distinction is made between, “soft regulatory rule-making” (involving para-law policy-steering instruments) and, “soft administrative rule-making” (involving post-legislative guidance instruments).⁷⁸ In the context of post legislative guidance issued under REACH, this distinction appears rather blunt.

Post-Legislative Guidance as Soft Law

As noted in the introduction to this Chapter, this thesis is particularly concerned with the use of post legislative guidance and the challenges it poses. However, save for detailed pieces by Scott and Senden (discussed below) little work has been undertaken in this area. Furthermore, many of the soft law examples used in the literature either act in the place of hard law or alongside hard law; few discussions concern where soft law is used to build on, and is often foreseen by, hard legislation. 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. For present purposes, the following definition used by Senden sets the broad limits of what this thesis is concerned with,

“Soft post legislative rule making concerns act 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.”⁷⁹

In this regard, these instruments fulfill what Senden referred to in her earlier work as a “post law function”.⁸⁰ In his review of EC competition policy, Hofmann notes that soft post legislative instruments can take a variety of forms/be called a number of

⁷⁷ *ibid*, 118

⁷⁸ Senden and van den Brink (n 48) 12

⁷⁹ Senden (n 48) 60

⁸⁰ Senden (n 12) 143-144

different things: guidelines, notices, letters, communications, codes etc.⁸¹ In this thesis, ‘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 but fulfill 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 in post legislative soft norms. These are discussed in detail in Chapter 9.

Despite the lack of academic focus, there has been an increase in the use of 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 increasing reliance on broad and imprecisely defined framework norms.⁸² Senden comments that such increase is reflective of the EU as a maturing regulatory system and mirrors what has occurred in the legal regimes of the Member States.⁸³ It may also be the case that this approach permits hard law to establish principles and objectives, leaving guidance to flesh out the necessary details. The attraction of guidance instruments is summarised by Scott as follows:

“They may be used to elaborate upon the meaning of framework norms, to compensate for a lack of legal competence, to overcome legislative deadlock, to adjust the institutional balance between institutions to or to inject a higher degree of regulatory agility than formal legislation can provide.”⁸⁴

Similarly, Harlow and Rawlings talk of a legal hierarchy which may need to be “amplified, interpreted or expanded by soft law”.⁸⁵ However, Senden notes that, even post the Lisbon Treaty, the TFEU and the TEU are silent on the existence of post legislative instruments (save for the Recommendation and the Opinion, discussed

⁸¹ Herwig Hofmann, ‘Negotiated and Non-Negotiated Administrative Rule-Making - The Example of EC Competition Policy’ [2006] 43 Common Market Law Review 153, 59

⁸² Scott (n 79) 330

⁸³ Senden (n 48) 61

⁸⁴ Scott (n 79) 353

⁸⁵ Harlow and Rawlings (n 47) 193

above).⁸⁶ In his broad review of new governance in EU, Armstrong writes that what is seen over time in the EU is a, “relocation of norm production and norm elaboration to a range of institutional locations outside of, but not unconnected to, the inter-institutional decision making processes associated with the Community Method.”⁸⁷ Here, he writes that, “alternative sites of norm production prevail in the post legislative ‘executive’ phase.”⁸⁸ Similarly, Hofmann talks of the Commission “regulating by information” through the use of post legislative guidance, shaping public and private activity.⁸⁹

Challenges of Post Legislative Guidance

In terms of competencies, the main challenge with post legislative guidance is where the line is drawn between legislative mandate and the operationalisation or implementation of legislation, “particularly under conditions of novel risks and uncertainty.”⁹⁰ Here, there are two risks: that the guidance goes beyond that which is mandated in the legislation (and so soft post legislative acts are used as a lawmaking device);⁹¹ and/or the guidance falls short of legal obligations laid down by the EU.⁹² The use of ‘and/or’ here is important and seeks to signal that guidance is not a single or static concept and may take a variety of forms, some more binding and more expansive than others. At the same time, and as demonstrated in Chapter 4, the roles of various actors in the production of ‘ECHA’ guidance (the Agency, the Commission, Member States, industry, other experts etc) mean that the familiar problems of ensuring accountable and effective executive governance are compounded in a situation where, “authorship and responsibility may be blurred rather than clearly allocated or delegated.”⁹³ This blurring is itself a product of the less than clear lines between legislative and executive action.⁹⁴ These challenges are

⁸⁶ Senden (n 48) 59

⁸⁷ Armstrong (n 4) 7

⁸⁸ *ibid* 13

⁸⁹ Hofmann (n 89) 177

⁹⁰ Armstrong (n 4) 13

⁹¹ Senden (n 48) 66

⁹² Here, Scott uses the example of guidelines produced in the context of the EU Emissions Trading Scheme and constraints placed on large hydroelectric power production projects. See Scott (n 78)

⁹³ Armstrong (n 4) 16

⁹⁴ Charles F Sabel and Jonathan Zeitlin, ‘Learning from Difference: The New Architecture of Experimentalist Governance in the EU’ (2008) 14(3) *European Law Journal* 271

discussed in more detail in Chapter 9, following the rigorous documentary analysis of REACH in Chapters 4-8.

Senden writes of the real problem of lack of control of the Commission and notes instances in which the Commission has engaged in post legislative norm making to the detriment of the position of the Council and the European Parliament in the decision making process.⁹⁵ Linked to this issue of accountability are concerns over transparency and whether the procedures which lead to the adoption of guidance are sufficiently open, particularly where the European Parliament is excluded from participation.⁹⁶ There is also the concern that the European Commission might exercise its powers of enforcement as a result of guidance which is not legally binding.⁹⁷ With REACH, there is the corollary concern that ECHA might exercise its regulatory functions (for example, acceptance or rejection of a Registration dossier) as a direct result of norms set out in its guidance documents which do not perhaps have the force of law.

Two key pieces on post legislative norm elaboration concern the Water Framework Directive (hereafter, the 'WFD').⁹⁸ The WFD sets out a series of environmental objectives and the broad stages which should be followed in order to achieve those objectives. It is, as the name of the instrument suggests, based primarily on framework norms which require further elaboration. In their exploration of the new governance approach of the WFD, Scott and Holder write of the differences between the "surface appearance" of the legislation which "belies a complex reality which is characterised by multi-level, experimentalist governance."⁹⁹ Much of the reality of the implementation of the WFD, they argue, "rests upon informal structures and recourse to soft law."¹⁰⁰ As part of a Common Implementation Strategy ('CIS') for the WFD, various forms of guidance have been issued. Scott and Holder refer to comments by

⁹⁵ Senden (n 48) 65

⁹⁶ Scott (n 79) 330

⁹⁷ *ibid*, 345

⁹⁸ Council Directive (EC) 2000/60 establishing a framework for Community action in the field of water policy OJ L 327/1

⁹⁹ Joanne Scott and Jane Holder, 'Law and New Environmental Governance in the European Union' in Grainne de Burca and Joanne Scott (eds) *Law and New Governance in the EU and the US* (Hart Publishing 2006) 226; William Howarth, 'Aspirations and Realities under the Water Framework Directive: Proceduralisation, Participation and Practicalities' (2009) 21(3) *Journal of Environmental Law* 391

¹⁰⁰ Scott and Holder (*ibid*)

the EEB that while these guidance documents can help to achieve the WFD objectives, “nevertheless, in a few cases, the guidance documents deviate from best practices and potentially undermine WFD requirements.”¹⁰¹ There is, in this sphere, the concern that the consensual nature of decision making underpinning the guidance, “generates a lowest common denominator approach.”¹⁰² Arguably, this has also been seen with REACH and the shift to a ‘majority rules’ as opposed to ‘consensus based’ form of decision making for ECHA’s guidance to get around this issue is notable.¹⁰³ Scott and Holder observe that one of the distinguishing features of the CIS is its provisionally and emphasis on change/learning from experience.¹⁰⁴ This, it is worth emphasising, is also seen with guidance produced under REACH (and is discussed in more detail in Chapter 4). What is striking about the WFD, and what this thesis aims to draw out in relation to REACH, are the elaborate collective processes for post legislative norm elaboration which span sites and levels of governance.¹⁰⁵ In his piece on the WFD, Howarth comments on the “strong technical character” of much of the Directive guidance and notes that it is written for a “regulatory audience” and not the general public.¹⁰⁶ This is echoed in much of that which is produced under REACH.

Conclusions

Post legislative norm elaboration via guidance provides challenges to and for law: to law, because it is not birthed in the same way or subject to the same scrutiny; and for law, because (as discussed above) its status and effect are uncertain until ex post facto review and potential crystallisation by the Courts. In her review of the large hydro guidelines, Scott comments on the lack of transparency in the processes leading up to the adoption of the guidance, which is compounded by the informal nature of drafting processes and the lack of participation by the European Parliament and EU NGOs.¹⁰⁷ She argues that these guidelines (and other forms of guidance more widely), “give

¹⁰¹ Scott and Holder (n 111) 230

¹⁰² *ibid*

¹⁰³ See Chapter 4

¹⁰⁴ Scott and Holder (n 111) 232

¹⁰⁵ Scott and Holder (n 111) 236

¹⁰⁶ Howarth (n 99) 410

¹⁰⁷ Scott (n 78) 348

rise to a form of complex normativity that combines European and national hard and soft law in a manner that presents a challenge for European administrative law.”¹⁰⁸

In other work (on the Water Framework Directive), Scott and Holder set out that the emergence of ‘experimentalist federalism’ in the EU, which is collaborative and multi-level with emphasis upon soft law (in opposition to the classic community method) “poses stark and difficult questions for law and for lawyers.”¹⁰⁹ They argue that it is not enough to simply note the existence of a gap between law and the practice of governance. Rather, the challenge also lies in, “contemplating the role of, and implications for, law in the face of shifting patterns in the practice of governance.”¹¹⁰ There are also fundamental concerns about how to square post legislative guidance with core principles of the EU. Here, Senden argues that the lack of explicit reference to soft post legislative instruments in the Treaty of Lisbon is,

“at odds with the way in which the Treaty of Lisbon has positioned the principles of openness, transparency, consultation and participation in Articles 11 TEU and 15 TFEU as standards for assessing the behavior of the EU institutions from the perspective of good administration and governance.”¹¹¹

One might argue that such lack of explicit reference is unimportant if those same principles are found, as a matter of fact, in the practices and processes put in place by the post legislative norm making entity. Here, Scott and Holder have argued that the CIS under the WFD (which has no basis in any legal act of the EU) represents an example of “embedded constitutionalisation,” where the practice of governance has spawned a process of constitutionalism from within, in which expectations are settled and core values (transparency, accountability, participation etc.) are set out.¹¹² However, they accept that a fundamental question of accountability remains: is decision-making taking place in a normative vacuum?¹¹³ Much may depend on outlook and, as Armstrong notes, whether one views legislation as a “framework for

¹⁰⁸ Scott (n 78) 354

¹⁰⁹ Scott and Holder (n 111) 212

¹¹⁰ Scott and Holder (n 111) 213

¹¹¹ Senden (n 48) 71

¹¹² Scott and Holder (n 111) 238

¹¹³ Scott and Holder (n 111) 239

norm development” or as a vehicle for detailed substantive rules.¹¹⁴ The pace of EU legislation and the demands on EU legislators most likely means that EU law can only ever be a framework for norm development, even where, as seen with REACH, the legislation partly comprises highly detailed rules as well as open ended norms. At the same time, Armstrong counsels that those who would champion experimentalist governance in the EU (including the use of post legislative norm elaboration) would, “do well to remember the over inflated optimism with which comitology was embraced as an ideal legal and institutional framework for the exercise of executive power.”¹¹⁵ What seems clear is that, as Senden and van den Brink observe, “no clear-cut answers exist with regard to the issue as to how to deal with soft rule-making, including by agencies.”¹¹⁶

Post Legislative Guidance and this Thesis

This thesis explores the challenges posed by post legislative norm elaboration via guidance issued under REACH. In the Chapters that follow, the various elements of REACH are explored (registration, evaluation, restriction etc). This is done on two fronts: (i) what the text of the Regulation says about each of those elements; (ii) and what the guidance that accompanies the Regulation says. This analysis shows that the wealth of guidance issued under REACH takes a variety of forms and performs a variety of functions. What is evident is that there is a hierarchy of norms within the broad umbrella of ‘guidance’ and that the same guidance document may amplify, interpret, expand, translate and/or contract the underlying legislation. To borrow a phrase from Scott referenced earlier in this Chapter, the “complex normativity” posed by REACH and its guidance creates a fascinating site of study.¹¹⁷ In order to fully understand the complexities and challenges posed by the use of guidance under the elements of REACH, however, it is first necessary to have a somewhat detailed sense of the entire Regulation. This necessary exposition follows in Chapter 3.

¹¹⁴ Armstrong (n 4) 36

¹¹⁵ Armstrong (n 4) 18

¹¹⁶ Senden and van den Brink (2013) 77

¹¹⁷ Scott (n 79) 354

CHAPTER 3

REACH – AN OVERVIEW OF THE REGULATION

Without fear of being accused of hyperbole, REACH is massive. Having been labelled (by the EU Commissioner who oversaw the five year progression from White Paper to agreed legislative instrument), as "possibly the most controversial and complex piece of legislation in European history"¹, the most recent consolidated version of the Regulation stands at 516 pages (over 130,000 words).² This is to say nothing of the more than 5,000 pages of official guidance on REACH produced by the European Chemicals Agency³ or the associated documents (too numerous to count) aiding at interpretation of the text produced by the Commission, EU political parties, the Member States, industry groups (such as those representing the chemicals sector at the EU and UK levels; CEFIC⁴ and the CIA⁵ respectively), NGOs and others (including, but not limited to, academics, lawyers in private practice and various forms of technical and scientific consultant).

Given this abundance of information aiming simply at describing REACH, the ambit of this Chapter is necessarily limited: to present the thousands of pages on the text of REACH in a summary format. In particular, the seventeen annexes to REACH, which set out in detail matters such as the breadth and depth of information required as part of the Registration process, will not be discussed to any great length, nor will comment be made on the fees and charges associated with REACH.⁶ The reader is also referred to the wider caveats in relation to this thesis outlined in Chapter 1. It is not the intention in this Chapter to detail every nuanced aspect of every provision of the Regulation. Rather, a broad picture of REACH will be painted in sufficient detail for the reader to be able to better understand the governance issues in the REACH

¹ Gunter Verheugen, EU Industry Commissioner. See: <<http://www.telegraph.co.uk/news/worldnews/europe/1503325/Most-controversial-European-law-wins-parliamentary-approval.html#>> accessed 10 August 2014

² See: <<http://echa.europa.eu/regulations/reach/legislation>> accessed 10 August 2014

³ See: <http://guidance.echa.europa.eu/guidance_en.htm> accessed 10 August 2014

⁴ See: <<http://www.cefic.be/en/REACH-implementation.html>> accessed 10 August 2014

⁵ See: <<http://www.reachready.co.uk/>> accessed 10 August 2014

⁶ On which, see Article 73 and Commission Regulation (EC) 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to REACH [2008] OJ L 107/6

context discussed in particular depth in Chapters 4-9. Despite these caveats, this Chapter is thick with detail, but unapologetically so and the reader is encouraged to reflect on the following by Scott in her own thorough review of the Regulation,

“The discussion which follows is often technical and dense. This is unavoidable when examining a regulatory regime of this volume and complexity. This should not be allowed to disguise either the intrinsic importance of the subject under discussion for environment and human health protection, or the fascination of the governance forms which this regulation embodies. It is in the minutiae of law’s construction of decision-making procedures and conditions for action that the politics of risk regulation are played out.”⁷

In terms of structure, this Chapter begins with a few words on REACH terminology before setting out the entire Regulation in two paragraphs by way of overview. The key ‘players’ in relation to REACH are introduced (with primary focus on the newly created regulator, ECHA) and the ambit of the Regulation discussed (here, with emphasis on those chemical substances that are excluded or exempted). Each substantive element of REACH (Registration, Evaluation, Authorisation and Restriction) is then set out in some detail. For the avoidance of doubt, references in this thesis (including in footnotes) to “articles” and “recitals” are, save where expressly stated otherwise, references to articles and recitals in REACH. In addition, references to “the Regulation” are, save where the context otherwise permits, references to REACH.

A Word On Terminology

REACH is a linguistically complicated legislative instrument, full of difficult terms and less than obvious acronyms. The Regulation requires one to know how ‘IUCLID’ relates to a ‘SIEF’; to be able to identify a ‘CMR’ from a ‘vPvB’; to understand that ‘CSR’ means something other than corporate social responsibility; and that an ‘OR’ is something wholly unrelated to hospitals (unless, of course, negotiations in a SIEF become overly heated). Even simple terms, like “manufacturer”, have meanings

⁷ Joanne Scott, ‘REACH: Combining Harmonisation with Dynamism in the Regulation of Chemicals’ in Joanne Scott (ed.), *Environmental Protection: European Law and Governance* (OUP 2009) 59

within REACH that may betray their common origins.⁸ It is impossible to fully understand REACH without also understanding (at least some of) its linguistic complexities. Given this, a glossary of acronyms and terms is included at the front of this thesis and the reader encouraged to re-review this list before proceeding. The following section provides a summary of REACH in two paragraphs. It is hoped that this will sit in the reader's mind while they wade through the more substantive summary of REACH that the remainder of this Chapter constitutes.

An Introductory Overview of REACH

At its most basic, REACH requires the generation of data on the intrinsic properties of certain chemical substances (around 45,000 of the 105,000 substances currently on the market)⁹ by the private sector (namely, the manufacturers, importers and, in limited circumstances, downstream users of those chemical substances) followed by the registration of such substances (accompanied by their testing data) with a new EU regulatory body, the European Chemicals Agency ("ECHA"). As set out in Chapter 1, unlike previous EU chemicals legislation, which saw Member States as the primary assessors of chemical safety, REACH is,

“based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.”¹⁰

It is thus for the private sector to ensure that such substances are, effectively, “safe”.¹¹ What data on a given chemical substance is required to be submitted to ECHA, and by when, depends on two main factors: (i) the volume of substance manufacture or import (the REACH registration obligation only applies to those substances

⁸ On which, see Article 3(9). Let us say, for example, that a company purchases chemicals and then turns these into paints, which it sells on the EU market. This company is not a manufacturer for the purpose of REACH, but rather a downstream user.

⁹ The exact number here is not known, due to certain ‘practical jokes’ which were played during the pre-registration phase which saw all 143,000 substances listed on EINECS pre-registered with ECHA. Pre-registration is discussed later on in the body of this Chapter, EINECS is detailed in Chapter 1 and more on these ‘practical jokes’ can be found here: <<http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx>> accessed 10 August 2014

¹⁰ Recital 16

¹¹ Article 1(3). Interestingly, “safe” is not defined in the Regulation or in ECHA’s guidance.

manufactured or imported in quantities greater than one tonne per annum¹²); and (ii) the intrinsic harmfulness of the substance. If no data is submitted for a substance subject to REACH, it can no longer be sold within the Union (a core REACH principle of “no data, no market”).

ECHA is tasked with providing guidance on the implementation and understanding of REACH, evaluating a limited amount of the data it receives and otherwise acting as a facilitator or intermediary between the private sector and the EU Commission (and Member States). Certain substances identified (either as a result of industry testing or via Member State nomination) as particularly harmful to human health or the environment will be banned (either in full or in certain applications); others may be granted a time limited authorisation by the Commission to remain on the market if it can be proved that the risks from those substances can be adequately managed, or where the use can be justified on socio-economic grounds and no suitable alternatives are available. Member States have individual responsibility for enforcement of the regime.

Cast List

There are various actors relevant to the implementation and operation of REACH.¹³ Many of these (Member States (and their competent authorities), NGOs, importers, manufacturers, consumers, the Commission) will be entities with which the reader is already familiar (albeit possibly in non-REACH contexts)¹⁴. Others (such as ECHA and Only Representatives) represent new entities created by REACH. The remainder of this section discusses ECHA only (and from a limited, institutional point of

¹² Other elements of REACH, such as the authorisation and restriction procedures, may apply to substances irrespective of the number of tonnes per year in which they are manufactured or imported. This is particularly relevant in the context of the application of REACH to nanomaterials (which operate on the one billionth scale and so may not be produced in sufficient volumes to trigger REACH Registration).

¹³ The actual ‘cast list’ is obviously much wider than that set out in this section. For example, no reference is made, at the EU level, to the Joint Research Centre which provides independent scientific and technological support for EU policy-making or, at the UK level, to bodies such as Local Authorities and HM Customs and Excise which have important roles to play in relation to enforcement of REACH.

¹⁴ As noted in the introduction to this Chapter, certain terms under REACH belie their common linguistic origins. The reader is thus encouraged to refer to the interpretive glossary at the front of this thesis.

view¹⁵). The reason for this is that to understand an Only Representative (or “OR”), it is first necessary to understand which entities have which obligations under REACH (a matter discussed in the body of this Chapter below). ORs are thus discussed in the section below on Registration. A more detailed review of what ECHA does (particularly as regards the creation, issue and amendment of guidance) appears in Chapter 4.

As has already been highlighted, with REACH came a new EU regulatory institution, the European Chemicals Agency or ECHA.¹⁶ Established given the “...need to ensure effective management of the technical, scientific and administrative aspects of [REACH] at Community level,”¹⁷ the Agency is intended to act, in many ways, as a conduit between the private sector, Member States, the Commission and other stakeholders (such as consumers and NGOs) relevant to the functioning of REACH. At the same time, ECHA is also a pro-active regulator and takes regulatory decisions (for example, on whether or not to accept a registration dossier). Recital 95 to the Regulation states that confidence in ECHA will only be secured if it is independent, transparent and efficient, with high scientific, technical and regulatory capacities. Various commentators have called into question whether in fact ECHA has the necessary competencies in order to carry out its mandates under REACH.¹⁸

On a structural level, REACH envisages three committees working as part of ECHA: a Member State Committee (which has the task of attempting to achieve agreement among Member States where a harmonised approach under REACH is required); a Committee for Risk Assessment; and a Committee for Socio-economic Analysis (both of which issue scientific opinions in certain contexts.)¹⁹ In addition, there is a Secretariat,²⁰ a Board of Appeal and a Forum for Exchange of Information on

¹⁵ The roles and responsibilities of ECHA under the substantive elements of REACH are discussed in relation to those substantive elements.

¹⁶ A word here on pronunciation. While those with English as their mother tongue tend to pronounce “ECHA” as “Etch-A”, the more common version is “Eck-Ah”.

¹⁷ Recital 15

¹⁸ See, for example, Ineke Gubbels-van Hal and Jacques Pelkmans, ‘Is REACH going well?’ (2009) CEPS Policy Brief 1

¹⁹ Recitals 102 and 103; Articles 76(1)(c), (d) and (e).

²⁰ The Secretariat, as the name may suggest, has responsibility for supporting the Management Board in administrative and certain technical matters. Recital 98 details that “In the interests of efficiency, the staff of the Agency Secretariat should perform essentially technical-administrative and scientific tasks without calling on the scientific and technical resources of the Member States.” This is no easy task

Enforcement (the “Forum”)²¹. The Forum is discussed in more depth in Chapter 8 (which summarises the enforcement of REACH in the UK from a structural level). The Agency is managed by a Management Board (the “Board”), led by an Executive Director.²² The Board comprises 28 Member State representatives, (one from each State), up to six representatives appointed by the Commission and two independent persons appointed by the Parliament.²³ The UK representative on the Board is John Roberts, head of Chemicals and Nanotechnologies at the Department for Environment, Farming and Rural Affairs. The tasks of the Board include the adoption of the work programme, an annual report and other strategic documents as well as the adoption of ECHA’s budget and the delivery of an opinion on the final accounts. The Board also appoints the Executive Director, the Board of Appeal and the members of the Committee for Risk Assessment and the Committee for Socio-economic Analysis, and may invite stakeholders to Committee meetings. The current Executive Director of ECHA is Geert Dancet, a Commission employee from 1986 – 2007 (who headed the REACH unit of DG Enterprise).

The ECHA Board of Appeal comprises three members, a Chairman and two others,²⁴ each appointed by the Management Board.²⁵ The three members (and their “alternates”, who represent the members of the Board of Appeal in their absence²⁶) must have appropriate technical and/or legal qualifications.²⁷ The matters for which an appeal may be brought before the Board are somewhat limited.²⁸ Article 91 details that an appeal may be brought against decisions of the Agency taken pursuant to

with an institution based in Helsinki, the media having reported on problems faced by ECHA in recruiting staff.

²¹ Articles 76(1)(f), (g) and (h)

²² Articles 76(1)(a) and (b)

²³ The list of current (October 2009) Board members can be found here:

<http://echa.europa.eu/about/organisation/management_board/management_board_members_en.asp> accessed 10 August 2014

²⁴ Article 89(1)

²⁵ Article 89(3)

²⁶ Article 89(2) It seems that ECHA have interpreted this provision of REACH widely and have appointed three legal and three technical “alternatives/additional members” in addition to the Chairman, the legally qualified member of the Appeal Board and the technically qualified member of the Appeal Board.

See: <http://echa.europa.eu/appeals/board_of_app/board_app_compos_en.asp> accessed 10 August 2014

²⁷ Commission Regulation (EC) 1238/2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency [2007] OJ L 280/10, Article 1

²⁸ For all other decisions of ECHA, an action may lie before the General Court (formerly the Court of First Instance) or Court of Justice of the European Union (formerly the European Court of Justice) (Article 94(1)).

Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 51 of REACH.²⁹ Those with standing to appeal comprise the usual suspects with standing elsewhere in EU law:³⁰ any natural or legal persons to whom a decision is addressed; and those persons to whom a decision is or direct and individual concern (even though not addressed to them.)³¹ Appeals must be brought within three months³² and decisions of the Board are subject to challenge before the General Court (formerly known as the Court of First Instance.)³³

ECHA is financed partly by fees paid by natural or legal persons under REACH (i.e. the fees paid for registration) and partly by the general budget of the European Communities.³⁴ It is also open to Member States to make “voluntary contributions” to the Agency.³⁵ ECHA was subject to a review by the Commission by 1 June 2012 and then every five years thereafter.³⁶ The conclusions of the 2012 REACH Review are discussed, where appropriate, in Chapters 5-9.

The Aims of the Regulation

REACH has three given (if not necessarily complementary) aims:³⁷

1. a high level of environmental and human health protection (with the broad, and ill defined, goal of “achieving sustainable development”);³⁸
2. furthering the free movement of substances; and

²⁹ Broadly, what this means is that the Board of Appeal may hear appeals in relation to the following matters: Exemptions from the general obligation to register for product and process orientated research and development; Rejections of registrations; Sharing of existing data in the case of registered substances; Sharing of data involving tests; Examination of testing proposals; Compliance check of registrations; and Substance evaluation. Each of these matters is set out in more detail in the body of this Chapter.

³⁰ On the area of the jurisdiction of the European Courts and the question of standing more generally, see Part IV of: Alan Dashwood, Michael Dougan, Barry Rodger, Eleanor Spaventa and Derrick Wyatt, *Wyatt & Dashwood's European Union Law* (6th edn, Hart 2011)

³¹ Article 92(1)

³² Article 92(2)

³³ Article 94(1)

³⁴ Recital 107, Article 96(1)(a) and (b)

³⁵ Article 96(1)(c)

³⁶ Article 75(2)

³⁷ Recital 1, Article 1(1)

³⁸ Recital 3

3. enhancing competitiveness and innovation.

These are stated as forming part of obligations on the EU under the Johannesburg World Summit³⁹ and the Strategic Approach to International Chemical Management.⁴⁰ At the same time, Article 2(4)(a) details that REACH is intended to apply without prejudice to EU workplace and environmental legislation,⁴¹ or to competition legislation (this latter element is discussed in more depth below in the section on SIEFs).⁴² It is envisaged that the data generated by REACH will have a direct impact on other areas of EU competence, such as product safety or eco-labelling.⁴³

The Ambit of REACH: Exclusions

The above introductory overview of REACH set out that the Regulation will likely capture around 45,000 of the over 100,000 substances currently on the EU market. However, certain substances are excluded from the ambit of REACH. Certain of these exclusions apply in full; others only exclude the class of substance from certain of the provisions of REACH.⁴⁴ This is perhaps one of the key deficits with the Regulation, in that it does not actually create a level playing field for chemicals risk assessment. Table 3.1 below sets out those substances which are excluded and the corollary reasons for such given by the Regulation.

³⁹ Pursuant to an implementation plan adopted on 4 September 2002. Recital 4.

⁴⁰ Adopted on 6 February 2006 in Dubai. Recital 6

⁴¹ Recital 5. Such legislation includes (but is not limited to): Council Directive (EC) 2004/37 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work [2004] OJ L 229/23; and Council Directive (EC) 98/24 on the protection of the health and safety of workers from the risks related to chemical agents at work [1998] OJ L 131/11

⁴² Recital 48

⁴³ Recital 14. On the issue of the interaction of REACH with product liability law, see: Paul Boden and Andrew, 'REACH and the Consumer Products Sector - Regulatory and Product Liability Implications of the EU's Chemicals Regime' in Ian Dodds-Smith and Michael Spencer QC (eds) *The International Comparative Legal Guide to Product Liability 2009* (Global Legal Group 2009)

⁴⁴ The Regulation uses both "excluded" and "exempted", but the difference between these two is not clear.

Table 3.1. Substances Excluded From REACH

Substance	Type of Exclusion	Justification and Commentary
Wastes	Full	Exclusion should “ensure workability and... maintain the incentives for waste recycling and recovery.” ⁴⁵
Substances under customs supervision which are in temporary storage, in free zones or free warehouses with a view to re-exportation or in transit.	Full	Such substances are not “used” as this term is understood within REACH. ⁴⁶
Dangerous substances and dangerous preparations carried by rail, road, inland waterways, sea or air.	Full	Specific legislation already applies to such carriage. ⁴⁷
Substances manufactured in the Community or imported for the purposes of product and process orientated research and development.	Articles 5, 6, 7, 17, 18 and 21 do not apply for a period of five years. This is, in short, an exemption from registration.	This exemption is granted to “encourage innovation.” ⁴⁸ Where seeking to take the benefit of this exemption, the relevant manufacturer or importer or producer needs to notify ECHA of certain information and pay the relevant fee. ⁴⁹
Substances used in medicinal products for human or veterinary use, ⁵⁰ or substances used in food or feedingstuffs in accordance with Regulation (EC) No 178/2002. ⁵¹	Provisions of Titles II, V, VI and VII do not apply. This means that such substances are excluded from the provisions on registration, evaluation and authorisation.	Such exclusion is necessary to “avoid confusion” between the mission of ECHA and the missions of the European Medicines Agency and the European Foodstuffs Agency. ⁵²

⁴⁵ Recital 11, Article 2(2)

⁴⁶ Recital 10, Article 2(1)(b)

⁴⁷ Recital 10, Article 2(1)(d)

⁴⁸ Recital 28, Article 9(1)

⁴⁹ Article 9(2)

⁵⁰ Article 2(5)(a), providing that such products are within the scope of Council Regulation (EC) 726/2004 on the Community code relating to veterinary medicinal products [2004] OJ L 136/1; and Council Directive (EC) 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L 311

⁵¹ Article 2(5)(b)

⁵² Recital 111

Substances which are necessary in the interests of defence.	Case-by-case specific	Member States may nominate certain substances for exemptions. ⁵³
Non-isolated intermediates. ⁵⁴	Full	An intermediate means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. ⁵⁵ A non-isolated intermediate means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. ⁵⁶
Polymers	Exclusion from Titles II and VI. This means that polymers are excluded from the requirements of registration and evaluation.	Exclusion lasts “until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria.” ⁵⁷ What this means, in layman’s terms, is that including polymers within REACH is thought to be too complicated for the present time. This topic was the subject of the first case on REACH before the UK and EU courts. ⁵⁸
Radioactive substances within the scope of Council Directive 96/29/Euratom of 13 May 1996. ⁵⁹	Full	There is no given reason for this exclusion in the text of REACH.
Substances included in Annex IV.	Exempted from Titles II, V and VI (i.e. from registration and evaluation).	It is thought that sufficient information is known about these substances that they are to be considered minimum risk because of their intrinsic properties. ⁶⁰ The list in Annex IV includes substances such as argon and sunflower oil.

⁵³ Article 2(3)

⁵⁴ Article 2(1)(c)

⁵⁵ Article 3(15)

⁵⁶ Article 3(15)(b)

⁵⁷ Recital 41

⁵⁸ See: *R (SPCM SA and Others) v Secretary of State for Environment, Food and Rural Affairs* [2007] EWHC 2610 (Admin); and *Case C- 558/07 S.P.C.M. and others* [2009] ECR I-05783

⁵⁹ Article 2(1)(a)

⁶⁰ Article 2(7)(a)

Substances covered by Annex V.	Exempted from Titles II, V and VI (i.e. from registration and evaluation).	Registration is deemed “inappropriate or unnecessary” for these substances and their exemption is not thought to prejudice the objectives of REACH. ⁶¹ Included in Annex V are substances which occur in nature (including natural gas, crude oil and minerals).
Substances on their own or in preparations, registered in accordance with Title II, exported from the Community by an actor in the supply chain and re-imported into the Community by the same or another actor in the same supply chain.	Exempted from Titles II, V and VI (i.e. from registration and evaluation).	There is no stated reason for this exemption in REACH (although it makes sense on a practical level.) ⁶² Note, however, that this ‘substances in the same supply chain’ exemption operates only in respect of registration (and not additionally pre-registration).
Substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community. ⁶³	Excluded from Titles II, V and VI (i.e. from registration and evaluation).	This “recovery” exemption is linked to the wastes exemption detailed above. Note, however, that this is a complex area and one in which the European Commission has published draft guidance. ⁶⁴
On-site isolated intermediates and transported isolated intermediates.	Excluded from: (a) Chapter 1 of Title II, with the exception of Articles 8 and 9; and (b) Title VII ⁶⁵ (i.e. exemption from certain aspects of registration and from the authorisation process).	An on-site isolated intermediate means an intermediate not meeting the criteria of a non-isolated intermediate (set out above) and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities. ⁶⁶ A transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites. ⁶⁷ Note, however, that any manufacturer of an on-site isolated intermediate or transported isolated

⁶¹ Article 2(7)(b)

⁶² Article 2(7)(c)

⁶³ Article 2(7)(d)

⁶⁴ See : <http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/waste_paper_ca_090403_en.pdf> accessed 10 August 2014

⁶⁵ Article 2(8)

⁶⁶ Article 3(15)(b)

⁶⁷ Article 3(15)(c)

		intermediate in quantities of 1 tonne or more per year is required to submit a limited registration to ECHA. ⁶⁸ This registration requirement is less burdensome than the more general requirements in Chapter 1 of Title II of REACH.
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In addition to the substances set out above, which are excluded from REACH, two other classes of substances are “to be regarded as registered” (and thus are effectively exempt from a large part of the active obligations on manufacturers and importers under the Regulation.)⁶⁹ The first class is certain substances manufactured or imported for use in “plant protection products” (namely, insecticides, herbicides, fungicides and other products);⁷⁰ the second class are those substances manufactured or imported for use in “biocidal products” (broadly, disinfectants, pesticides, preservatives and other products.)⁷¹

Where substances are to be “regarded as registered”, the Commission is obliged to send to ECHA the equivalent body of information as would be required were that substance subject to the registration provisions of REACH.⁷² The requirements and mechanics of registration (and optional pre-registration) under REACH are discussed in the following paragraphs.

⁶⁸ Articles 17 and 18

⁶⁹ Article 15

⁷⁰ Article 15(1) provides as follows: “Active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to Directive 91/414/EEC or in Regulation (EEC) No 3600/92, Regulation (EC) No 703/2001, Regulation (EC) No 1490/2002, Decision 2003/565/EC and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.”

⁷¹ Article 15(2) provides as follows: “Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market or in Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.”

⁷² Article 16(1)

Pre-Registration

The cornerstone of REACH is registration, the process by which (certain) manufacturers and importers of (certain) substances send (certain) information to ECHA. This is a massive undertaking: potentially millions of companies across the EU sending highly technical data to a regulator based in Helsinki with well-known staffing and budgetary issues (as noted above). The obligation to register chemicals under REACH with ECHA operated as from 1 June 2008. However, in order to “avoid overloading authorities and natural or legal persons with the work arising from [such] registration”,⁷³ REACH provided for a series of staggered registration compliance deadlines for what it terms “phase-in substances”.⁷⁴ Such staggered compliance deadlines were also intended to smooth the full entry into force of REACH and to allow relevant parties to “focus resources in the preparation for new duties at the right times.”⁷⁵ To take advantage of these deadlines, manufacturers and importers were required to pre-register their substances between 1 June 2008 and 1 December 2008.⁷⁶

The staggered compliance deadlines for registration, and the “phase-in substances” to which they relate, are set out below in Table 3.2. They are based on two principles: (a) chemicals manufactured in high volumes are likely to present greater risks to human health and the environment and so should be registered (and thus assessed) first; and (b) a degree of priority for chemicals of higher concern.

Table 3.2 – REACH Compliance Deadlines

Substances	Registration Deadline
Phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, in accordance with Directive 67/548/EEC ⁷⁷ and manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once after 1 June 2007.	1 December 2010

⁷³ Recital 42

⁷⁴ Detailed in Article 23

⁷⁵ Recital 127

⁷⁶ Article 28(2)

⁷⁷ The reader will recall that these terms and the ambit of Directive 67/548/EEC are discussed in depth in Chapter 1.

Phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC, and manufactured in the Community or imported in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007.	1 December 2010
Phase-in substances manufactured in the Community or imported, in quantities reaching 1 000 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007.	1 December 2010
Phase-in substances manufactured in the Community or imported, in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007.	1 June 2013
Phase-in substances manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once after 1 June 2007.	1 June 2018

Chapter 1 detailed that the chemicals regime prior to REACH divided substances into those “existing” and those “new”, with rigorous testing regimes in place solely for “new” substances. While REACH does not have such a divide, it does split substances between those which are “phase-in” (and which may benefit from the staggered registration compliance deadlines set out above if pre-registered) and “non-phase-in” substances (which were required to be registered before 1 June 2008 in order to stay on the market). Article 3(20) details that a “phase-in” substance is one which meets at least one of the following criteria:

1. It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). In theory, EINECS details all substances on the Community market on 18 September 1981; or
2. It was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of REACH, provided the manufacturer or importer has documentary evidence of this; or
3. It was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of REACH by the manufacturer or importer and was considered as

having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in REACH, provided the manufacturer or importer has documentary evidence of this. These substances are commonly referred to as “no longer polymers”.

The mechanics of pre-registration under REACH were relatively straightforward (and the process itself was free of charge). Article 28(1) details that in order to benefit from the transitional regime, each potential registrant of a “phase-in substance” manufactured or imported in quantities of 1 tonne or more per year was required to submit all the following information to the Agency by way of pre-registration:

- (a) the name of the substance;
- (b) his/her name and address and the name of a contact person at the manufacturer or importer; and
- (c) the envisaged deadline for registration of the substance (and the associated tonnage band in which the substance is manufactured or imported).

It is worth noting that the staggered registration deadlines for phase-in substances having undergone pre-registration are deadlines and not goals: it is perfectly possible for a manufacturer or importer to submit a registration at any time before the associated deadline.⁷⁸

Registration

One of the most fundamental tenets of the Regulation, the principle of ‘no data, no market’, details that substances on their own, in preparations or in articles may not be manufactured in the Community or placed on the market unless they have been registered with ECHA in accordance with Title II of REACH.⁷⁹ “Substances” are defined as “chemical elements and their compounds”, either manufactured or in a

⁷⁸ Article 23(4)

⁷⁹ Article 5

natural state;⁸⁰ “preparations” are a mixture of two or more substances;⁸¹ and “articles” are objects which have been given specific shapes, surfaces or designs during their production which determine their function to a greater degree than does their chemical composition (so, for example, the hard copy bound version of this thesis would be an article.)⁸² The potential breadth of REACH is thus staggering, capturing not only chemical manufacturers, but a wealth of chemical importers and a variety of chemical users as well as the producers of certain products (or articles, to give them their REACH moniker). Indeed, it is hard to think of many EU entities not impacted in some way by the Regulation (as, even if such has no direct obligations under REACH, its supply chain will, at some point, depend on chemicals manufactured in or imported into the EU).

For the avoidance of doubt, it is the substance (and not the preparation or the article) which requires registration under REACH. Registration is seen as acting as proof of compliance, with the obligations on manufacturers and importers to generate data on chemicals, assess risks arising from such data and then develop appropriate risk management techniques.⁸³ What is less clear is whether registration automatically discharges the duty of care that REACH imposes on manufacturers and importers to see that chemicals which they place on the market do not adversely affect human health or the environment.⁸⁴ There is little writing on this aspect of REACH, with commentators suggesting that the ‘duty of care’ in the Regulation “may” mean that manufacturers need to warn of inherent dangers in the chemicals they produce.⁸⁵

Registration obligations are volume triggered. With substances, the registration obligation rests on any manufacturer or importer of a substance, either on its own or in one or more preparation(s), who manufactures or imports in quantities of 1 tonne or more per year.⁸⁶ Thus, those who manufacture or import in quantities less than 1 tonne per year will not be obliged to register; although they may still be subject to the

⁸⁰ Article 3(1)

⁸¹ Article 3(2)

⁸² Article 3(3)

⁸³ Recital 19

⁸⁴ Article 1(3)

⁸⁵ Lucas Bergkamp, *The European Union REACH Regulation for Chemicals: Law and Practice* (OUP 2013) 296

⁸⁶ Article 6(1)

authorisation and/or restriction procedures, detailed below. With articles, any producer,⁸⁷ or importer, is required to submit a registration to the Agency for any substance contained in those articles, if both of the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year; and
- (b) “the substance is intended to be released under normal or reasonably foreseeable conditions of use.”⁸⁸

The obligation to register operates in respect of each legal entity within the Community manufacturing or importing a substance or article captured by REACH. So, for example, if a US chemicals manufacturer has three subsidiaries (one in the UK, one in France and one in Germany), each of which imports the same chemical from the US parent in amounts greater than one tonne per year, *each* subsidiary will be responsible to register that substance with ECHA. This example is also illustrative of the potential for the use of “Only Representatives” or “ORs” referenced earlier on in this Chapter. Say our US chemicals manufacturer also sells certain of its chemicals to a non-group company based in Spain. Under REACH, this Spanish company (as importer) would have the obligation to register the US company’s chemicals that it imports. However, where a manufacturer of substances or producer of articles is based outside of the EU, it may choose to appoint an “Only Representative” or “OR” to fulfill the obligations of its EU based importer.⁸⁹ If an OR is appointed, the OR (and not the importer) is the entity responsible for registration of the substance imported. On a practical level, a non-EU based exporter may choose to appoint an OR to prevent the exchange of certain confidential information with its EU based importer, or to retain control over the registration process. Any OR appointed must have a sufficient background in the practical handling of substances and the

⁸⁷ Defined in Article 3(4) as any natural or legal person who makes or assembles an article within the Community.

⁸⁸ Article 7(1). These words have proven difficult for ECHA and the Commission, who have declined to publish an exhaustive list of articles which are within the ambit of REACH and those without. However, some guidance on articles may be found here:

<http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf> accessed 10 August 2014

⁸⁹ Article 8(1)

information related to them,⁹⁰ and when an OR has been appointed, importers “within the same supply chain” need to be informed.⁹¹ What seemed to be a fairly simple procedure was muddied during the pre-registration phase of REACH by a lack of clear guidance from ECHA on: (a) the mechanics of OR appointment;⁹² (b) the levels of necessary qualification of the OR; and (c) what “within the same supply chain” means.⁹³ These issues have now been clarified somewhat through the publication of limited guidance in the ECHA Guidance on Registration document, but the example is an interesting one of the Agency’s guidance lagging behind.⁹⁴

On a substantive level, those obliged to register are required to submit a registration dossier, containing: (a) a technical dossier; and (b) for all substances manufactured or imported in quantities greater than ten tonnes per year per registrant, a chemical safety report (“CSR”).⁹⁵ Articles 10 and 12 and Annexes VI to XI of REACH detail the specific content of the technical dossier. Exactly what information is required to be submitted to ECHA depends on the ‘tonnage band’ (i.e. the number of tonnes per year of substance manufactured or imported per manufacturer or importer), with the higher the tonnage, the more information required. The tonnage bands relevant to REACH are as follows: one tonne or more per year; ten tonnes or more per year; one hundred tonnes per year or more; and one thousand tonnes per year or more.⁹⁶ Article 14 and Annex I detail the substantive content of the CSR. Essentially, the CSR documents the chemical safety assessment of the substance to be registered in the context of various environmental hazards, including (where required) a focus on exposure and related risks.

⁹⁰ Article 8(2)

⁹¹ Article 8(3)

⁹² For example, although REACH applies at the level of individual legal entity, would it be possible for the parent of a group of companies to appoint an OR for and on behalf of each member of that group based outside of the EU? Would a letter of appointment suffice? The author is aware, from contacts in private legal practice, of these simple issues (and others) on which there was a lack of definitive guidance from ECHA and/or the national helpdesks.

⁹³ Did it, for example, oblige notification of indirect parties such as the third downstream user of your direct importer, whose identity you may well not know and have no right to know?

⁹⁴ See:

<http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm?time=1257094752>
accessed 10 August 2014

⁹⁵ Article 10(1)

⁹⁶ The choice of these bands (and not, for example, 1 – 25 tonnes, 25 – 100 tonnes, 100 – 500 tonnes or some other scale) seems fairly arbitrary. There is no given reason in REACH why such were chosen.

It is worth noting here that the provision of information to ECHA is not a once and for all time obligation (and such is discussed in more depth in Chapters 5 and 6). Rather, following registration, a registrant shall be responsible “on his own initiative” for updating his registration without undue delay with relevant new information and submitting it to the Agency in various (and fairly broad) cases: some linked to mechanical changes (e.g. an importer becomes a manufacturer or vice versa or a change in the tonnage of substance manufacture or import); others linked to the intrinsic properties of the substance (e.g. new knowledge of the risks of the substance or new, previously unidentified, uses of the substance.)⁹⁷

Joint Submission of Registration Data: SIEFs and Data Sharing⁹⁸

Let us take a simple example, which will be used in other contexts throughout this thesis. Say we have ten manufacturers in the EU of (the hypothetical chemical) *legalene*, a highly catalytic substance used in the production of inks for the printing of law textbooks. Each manufactures in quantities greater than one tonner per year and *legalene* is not excluded from the ambit of REACH. Each manufacturer has pre-registered *legalene* as a phase-in substance with ECHA. The ten manufacturers now come to the task of registration. REACH operates on the principle of “one substance, one registration.” On a practical level, and with the aims of reducing chemical assessment testing (in particular, testing on animals),⁹⁹ and the associated cost to industry¹⁰⁰ REACH mandates the sharing of certain data between those manufacturers and importers intending to register the “same” substance. “Same” is in quotation marks here, as there may be complicated questions over whether Substance A and Substance B are the same, even where they share a common name or classification or EINECS entry. This issue is explored in more depth in Chapter 5 of this thesis. Data sharing is facilitated by a SIEF (or Substance Information Exchange Forum), membership of which is compulsory for all potential registrants of the “same” substance (manufacturers, importers and Only Representatives) and optional for downstream users of the substance and other third parties who have submitted

⁹⁷ Article 22(1)

⁹⁸ This section uses the example of data sharing in the context of a pre-registered phase-in substance. For non phase-in or non pre-registered substances, Articles 26 and 27 govern the data sharing process.

⁹⁹ Article 25(1)

¹⁰⁰ Recital 33

information to ECHA on that substance.¹⁰¹ Thus, in our example, all ten *legalene* manufacturers will be members of the *legalene* SIEF. The ultimate aim here, under the “one substance, one registration” principle, is that one member of the SIEF (commonly referred to as the “lead registrant”) will make a submission to ECHA of the data on the intrinsic properties of *legalene* for and on behalf of all the other members of the SIEF (thus obviating the need for, here, ten separate submissions of a registration dossier for *legalene*.)¹⁰²

REACH does not mandate the legal form of the SIEF nor how the SIEF members are to organise themselves.¹⁰³ Across the EU, different SIEFs have taken on different forms: some remain as unincorporated associations operating as a consortium and linked by various layers of contractual agreement; others have incorporated as limited liability companies; others partnerships; and a very small number as European Economic Interest Groupings. SIEFs are discussed in much more depth in Chapter 5. Whatever the format of the SIEF, the obligations of the SIEF participants are fourfold: (a) to provide other participants with existing studies on the intrinsic properties of the SIEF substance; (b) to react to requests by other participants for information; (c) to collectively identify needs for further studies; and (d) to arrange for those studies to be carried out.¹⁰⁴ Each SIEF is required to be operational until 1 June 2018 (i.e. until the final deadline for registration of substances under REACH.)¹⁰⁵ In terms of the approach to chemical testing that must be taken within a SIEF, REACH attempts to promote the use of “alternative test methods” not involving the use of vertebrate animals where data on the intrinsic properties of a substance is not already available.¹⁰⁶ Such methods should be used “whenever possible,”¹⁰⁷ with tests on vertebrate animals undertaken “only as a last resort.”¹⁰⁸

¹⁰¹ Article 29(1). Third parties with information on a substance may include (for example) NGOs who desire to participate in the registration process for a given substance and/or manufacturers or importers of a substance who manufacture below the registration volume trigger (i.e. one tonne per year).

¹⁰² Article 11(1)

¹⁰³ Indeed, a SIEF itself has no legal status. It is merely a forum for data exchange.

¹⁰⁴ Article 29(3)

¹⁰⁵ Article 29(3)

¹⁰⁶ Recitals 40 and 47

¹⁰⁷ Article 13(1)

¹⁰⁸ Article 25(1). This is primarily a response to concerns from animal welfare groups (among others) that arose during the negotiations of the Regulation in response to a claim that almost 4 million animals could be used to generate the necessary testing information under REACH. See, for example: <<http://news.bbc.co.uk/1/hi/world/europe/4437304.stm>> accessed 10 August 2014

In certain instances, the failure by a registrant to share data held by it (e.g. testing data on vertebrate animals) within the SIEF will lead to that registrant being unable to register its substance under REACH until he provides the information to the other participants.¹⁰⁹ Such data owner may be penalised according to national laws on REACH enforcement.¹¹⁰ Once data is submitted as part of registration, another manufacturer or importer may use that data for the purpose of their own registration for up to 12 years from submission.¹¹¹

Although it is stated that the operation of REACH, “... should be without prejudice to the full and complete application of the Community competition rules,”¹¹² the gathering together of, as in the earlier example, all ten of the EU’s *legalene* manufacturers in one place over a sustained period of time, with a legal mandate to share information, is of obvious potential concern. Article 25(2) states,

“The sharing and joint submission of information in accordance with this Regulation shall concern technical data and in particular information related to the intrinsic properties of substances. Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.”

The practicalities of policing the exchanges of data within a SIEF are, however, another matter. These concerns, and others in the context of SIEFs, are discussed in much more depth in Chapter 5.

Evaluation

Let us say that it is 2015 and our ten *legalene* manufacturers have pooled their information on the intrinsic properties of *legalene*, arranged for the necessary additional chemical assessment studies to be undertaken and sent the registration dossier to ECHA. The Agency will then assign a number to the registration,¹¹³ such that it can be easily identified, and undertake a completeness check in order to ascertain that all the elements required by REACH have been provided.¹¹⁴ The

¹⁰⁹ Article 30(3)

¹¹⁰ Article 30(6), Article 126

¹¹¹ Article 25(3)

¹¹² Recital 48

¹¹³ Article 20(1)

¹¹⁴ Completeness checks are undertaken for every registration sent to ECHA.

completeness check is not in any way substantive and amounts, in essence, to a “Are there electronic files that look as though they should be the right files under REACH in the dossier?” check. It should be stressed that the completeness check does not include an assessment of the quality or the adequacy of any data submitted to ECHA.¹¹⁵ Instead, it is (quite simply) a box checking exercise. The completeness check is required to be undertaken within three weeks of submission of registration and, where the check highlights incomplete or missing data from a registration, the registrant will be informed of this by the Agency and given a “reasonable deadline” to submit an amended, hopefully complete, registration.¹¹⁶

After registration (and a successful completeness check), ECHA will then evaluate (or assess) a certain number of registration dossiers and registered substances. Evaluation is said to be required in order to,

“...instil confidence in the general quality of registrations and to ensure that the public at large as well as all stakeholders in the chemicals industry have confidence that natural or legal persons are meeting the obligations placed upon them.”¹¹⁷

The Evaluation processes are split into two parts: (a) dossier evaluation; and (b) substance evaluation. Dossier evaluation is itself then split into two sub-categories: (i) a compliance check (not to be confused with the completeness check detailed above); and (ii) an examination of testing proposals. Compliance checks are intended to take place for no fewer than 5% of all registration dossiers received for each tonnage band.¹¹⁸ Without wishing to state the overly obvious, this means that up to 95% of all registration dossiers sent to ECHA will never undergo any form of evaluation (other than the completeness check box ticking exercise). This is discussed in more depth in Chapter 6.

ECHA comments that, “Substance evaluation aims to clarify any grounds for considering that a substance constitutes a risk to human health or the environment.”¹¹⁹

¹¹⁵ Article 20(2)

¹¹⁶ Article 20(2)

¹¹⁷ Recital 65

¹¹⁸ Article 41(5), although the Commission has the power to vary this percentage in accordance with Article 41(7)

¹¹⁹ This quotation was taken from ECHA’s ‘Guidance on Dossier and Substance Evaluation’ which is now said to be “obsolete”. See: < <http://echa.europa.eu/guidance-documents/guidance-on-reach>>

As a first task, ECHA (in co-ordination with the Member States), is obliged to develop criteria for prioritising substances, on a “risk based” approach, with a view to further evaluation.¹²⁰ These criteria (based on hazard information, exposure information and substance tonnage) will lead into a three year Community rolling action plan (the first submitted by ECHA to the Member States before 1 December 2010) detailing the substances to undergo substance evaluation each year and which Member State has responsibility for evaluating which substance.¹²¹ With substance evaluation, the role of ECHA is one of co-ordination, with the active evaluation undertaken by competent authorities in the Member States (or third parties appointed on their behalf)¹²². This form of evaluation is also explored in more depth in Chapter 6.

Authorisation

As outlined in Chapter 1, one of the reasons for the introduction of REACH was the lack of substantive data on the intrinsic properties of more than 99% of all chemicals on the EU market. One of the (albeit implicit) aims of the Regulation is to identify chemicals of concern and either remove them from the market or have their presence on the market subject to certain limitations, with the greatest focus on the substances of the highest concern.¹²³ For substances of “very high concern”, or “SVHCs” as REACH terms them, a time limited authorisation may be required from the Commission to allow them to remain on the EU market.¹²⁴ Certain SVHCs will be banned in full, under the Restriction procedure of REACH discussed below. Applicants seeking an authorisation for a SVHC will have to demonstrate that risks associated with uses of the substance are adequately controlled or that the socio-economic benefits of their use outweigh the risks. Applicants must also analyse whether there are safer suitable alternatives or technologies. If there are, then the applicant must prepare substitution plans and, if not, then they should provide

accessed 10 August 2014. Chapters 5 and 10 discuss ECHA’s updates to and removal of its own guidance documents in more depth.

¹²⁰ Article 44(1)

¹²¹ Article 44(2). It is worth noting that a Member State can put itself forward as the competent authority for evaluating a particular substance in accordance with procedures detailed in Article 44(2) and (3).

¹²² Article 45(1)

¹²³ Recital 115

¹²⁴ Article 56(1)

information on research and development activities to create alternatives to the SVHC, where appropriate.¹²⁵ The aim with authorisation is to ensure that SVHCs “are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.”¹²⁶ It is commonly thought that the authorisation process will apply to around 3,000 substances.¹²⁷

Not every SVHC will require authorisation. Those which do are detailed later on in this section. Article 57 lays down broad guidelines for the substances which may be considered as SVHCs (and thus potentially needing authorisation). These guidelines include the following three wide categories of substance:

1. Those meeting the criteria for classification as carcinogenic category 1A or 1B, mutagenic 1A or 1B, or toxic for reproduction category 1A or 1B in accordance with Annex I to the CLP Regulation; or
2. Substances which are persistent, bioaccumulative and toxic (or very persistent and very bioaccumulative) in accordance with the criteria set out in Annex XIII of REACH; or
3. Substances (such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties) which do not fulfil the criteria of the first two broad categories, but for which there is “scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern”¹²⁸. Such “other” substances will be identified on a case-by-case basis in accordance with a procedure set out in Article 59.

¹²⁵ Article 55

¹²⁶ Article 55

¹²⁷ See, for example, the reference to this number made here by the European Parliament:

<<http://www.europarl.europa.eu/sides/getDoc.do?language=EN&type=IM-PRESS&reference=20061213IPR01493>> accessed 10 August 2014

¹²⁸ Article 57(f)

The mechanics of how a substance becomes labeled a SVHC worthy of authorisation are somewhat laborious.¹²⁹ The two first steps are the identification and inclusion in a "Candidate List" of Substances of Very High Concern, and the prioritisation of substances to be included in Annex XIV of REACH (the "Authorisation List "). With the first step, Member States Competent Authorities (or ECHA, on a request by the Commission) have the ability to prepare dossiers for the identification of substances of very high concern (i.e. dossiers which contain chemical assessment data supporting the view of that Member State that the substance is of very high concern). These dossiers are then reviewed by ECHA, with the outcome of this identification procedure a list of substances (the above referenced Candidate List) which are candidates for eventual inclusion in the Authorisation List. This first step is not a once and for all time occurrence. Rather, it is intended that Member States will (on a regular, as yet undisclosed, basis) send dossiers detailing substances they consider to be SVHCs to ECHA. From the Candidate List, a number of substances will be prioritised for authorisation.¹³⁰ Priority is expected to be given to substances with: (a) PBT or vPvB properties; or (b) wide dispersive use; or (c) those manufactured or imported in high volumes.¹³¹ What prioritisation means, as a matter of practice, is that ECHA chooses which chemicals appear to be of the most concern to it (from the list of SVHCs generated by Member States) and sends the dossiers for those chemicals to the Commission who will make a decision on: (a) whether or not the substance will be subject to authorisation; (b) which uses of the included substances will not need authorisation (e.g. because sufficient controls established by other legislation are already in place); (c) and the "sunset date" by when a substance can no more be used without authorisation.

For certain SVHCs, an authorisation will be granted by the Commission if the applicant can demonstrate that the risk from the use of the substance is adequately controlled.¹³² For certain other substances,¹³³ an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the

¹²⁹ And are set out in Article 59

¹³⁰ The First Candidate List prioritised 7 substances for authorisation from a candidate list of 15. See: <http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_subst_inclusion.pdf> accessed 10 August 2014

¹³¹ Article 58(3)

¹³² Article 60(2)

¹³³ Listed in Article 60(3)

environment arising from the use of the substance and if there are no suitable alternative substances or technologies.¹³⁴ Article 60(5) details that when assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including:

- (a) whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures; and
- (b) the technical and economic feasibility of alternatives for the applicant.

Once granted, authorisations may be reviewed at any time if: (a) the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or (b) new information on possible substitutes becomes available.¹³⁵

While the Commission is the body with the power to grant an authorisation, the application for authorisation is made to ECHA,¹³⁶ and can be by one or more persons (including by the manufacturer(s), importer(s) and/or downstream user(s) of the substance.)¹³⁷ Similarly, applications can relate to one or more than substances (where such meet the definition of a group of substances in section 1.5 of Annex XI of REACH) and be for the applicant's own use(s) or the use(s) for which he intends to place the substance on the market.¹³⁸ The contents of the authorisation application are set out in Article 62(4) and include, in particular, an analysis of suitable alternatives to the substance (and, where such exist, a plan for substituting the substance with the alternative and an indicative timeline in which this will happen). Where there are subsequent applications for authorisation which could draw on data contained within a previous application, a subsequent applicant may refer to the appropriate parts of the previous application provided he has permission from the previous applicant.¹³⁹

¹³⁴ Article 60(4)

¹³⁵ Article 61(2)

¹³⁶ Article 62(1)

¹³⁷ Article 62(2)

¹³⁸ Article 62(3)

¹³⁹ Article 63(1)

Following submission of the application, ECHA will acknowledge receipt and its Committees for Risk Assessment and Socio-economic Analysis then have ten months (from the date of application) within which to give their draft opinions¹⁴⁰ (with the option to request additional information from the applicant, as may be necessary.)¹⁴¹ The draft opinions are sent to the applicant, with the option to comment, and then, once finalised, to the Commission, Member States and the applicant. The mechanics of this process and associated timeline are set out in Article 64(5). Within three months of receipt by the Commission of the opinions from ECHA, it will prepare a draft authorisation decision.¹⁴² A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article 133(2). Summaries of the Commission decisions, including the authorisation number and the reasons for the decision, in particular where suitable alternatives exist, are to be published in the Official Journal of the European Union and will be made publicly available in a database established and kept up to date by ECHA.¹⁴³

Where an authorisation has been made, the holder must include the authorisation number on the label before they place the substance or a preparation containing the substance on the market for an authorised use.¹⁴⁴

Restriction

In certain instances, the Authorisation procedures will not be enough to protect the environment or living organisms from the risks posed by certain substances. This may be because of the length of time which Authorisation can take and/or because of the level of potential threat to human health or the wider environment. Given this, REACH contains a Restriction process to regulate the manufacture, placing on the market or use of certain substances within the EU territory if they pose an unacceptable risk to health or the environment.¹⁴⁵ Such activities may be limited or even banned, if

¹⁴⁰ Article 64(1)

¹⁴¹ Article 64(3)

¹⁴² Article 64(6)

¹⁴³ Article 64(9)

¹⁴⁴ Article 65

¹⁴⁵ Article 68

necessary. ECHA comments that, “The restriction is designed as a “safety net” to manage risks that are not addressed by the other REACH processes.”¹⁴⁶

Any substance on its own, in a preparation or in an article may be subject to restrictions if it is demonstrated that risks need to be addressed on a Community-wide basis. Restrictions of a substance can apply to all uses or to specific uses. All uses of a restricted substance which are not specifically restricted are allowed under REACH unless they are subject to authorisation, or other Community or national legislation regulating their use. Unlike the Registration of substances under REACH (as set out above), there is no tonnage threshold for a substance to be subject to restriction.

Proposals for restrictions will be prepared by Member States or by ECHA (on request of the Commission) in the form of an Annex XV dossier.¹⁴⁷ The Annex XV dossier should demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and should identify the most appropriate set of risk reduction measures. Interested parties will have an opportunity to comment and the Agency will provide opinions on any proposed restriction.

Where a substance is subject to Restriction, it will be listed in Annex XVII of REACH. Substances which were already banned (in full or in certain applications) under pre-REACH EU law,¹⁴⁸ such as asbestos fibres, mercury, arsenic etc, have been grandfathered into Annex XVII.¹⁴⁹

Conclusions

This Chapter has sought to provide the reader with a sufficiently detailed overview of REACH to be able to engage fully with the commentary on the Regulation and the guidance produced on it by ECHA, as detailed in Chapters 4-8. Across the EU we do not have enough information on the intrinsic properties of the vast majority of

¹⁴⁶ See: <http://guidance.echa.europa.eu/restriction_en.htm> accessed 10 August 2014

¹⁴⁷ Article 69

¹⁴⁸ As contained in Council Directive (EEC) 76/769 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations [1976] OJ L 262 (commonly known as the ‘Limitations Directive’). The Limitations Directive was discussed in more depth in Chapter 1.

¹⁴⁹ Recital 84. Article 139 repeals the Limitations Directive as from 1 June 2009.

substances on the market to be able to judge whether or not they may adversely affect human health or the environment. REACH aims to address this data gap by transferring the regulatory burden for substance testing to the private sector and making compulsory the registration of such testing data with a central EU body, ECHA. This shift, from public sector to private sector, of the responsibility for evaluating the intrinsic nature of substances is important and reflects an (implicitly acknowledged) asymmetry of resources (both financial and in terms of human capital), expertise and information. With this shift comes an elaborate and complex piece of legislation accompanied by thousands of pages of equally elaborate and complex guidance.

REACH is complex and complicated, on a variety of levels legal and technical. It operates using various structural tiers (Registration, Evaluation, Authorisation, Restriction) with a blend or hybrid of regulatory approaches. The Regulation also creates a complex of structures within which a web of entities (private, public and not-for-profit; EU, non-EU and national) operate, with certain relationships obligatory and others optional. Some of these relationships (such as those created by the mandatory SIEF groupings) highlight extra-legal considerations and expose tensions between the regulatory burdens imposed by REACH (here, primarily in relation to data sharing) and market burdens imposed by competition between the manufacturers or importers of the same substance in the same geographic area.

In terms of ambit, the regulatory compass under REACH has asymmetrical capture: in certain instances (for example, with the Restriction and Authorisation processes) any chemical substance anywhere on the EU market may be subject to the provisions of the Regulation; in others (primarily with Registration) only one part of the spectrum of substances on the market is captured (due to tonnage criteria). Even with those substances subject to Registration, the regulatory burden widens or narrows (in terms of the breadth of the registration data required) as a function of tonnage bands and the intrinsic properties of the substance being registered. At the same time, there are a large number of exclusions. Such widening and narrowing of ambit under REACH highlights the potential overlapping nature of the Regulation with other forms of EU substance control, the complexity of legislating in this area, a lack of limitless resources and a desire not to stifle or inhibit innovation or the EU chemicals market

more than is strictly necessary to protect human health or the environment. Having considered the various elements of REACH, the following Chapter looks in depth at ECHA and the Agency's role in relation to the Regulation.

CHAPTER 4

THE EUROPEAN CHEMICALS AGENCY

With REACH comes a new EU regulator, the European Chemicals Agency, or ECHA. Established given the “...need to ensure effective management of the technical, scientific and administrative aspects of [REACH] at Community level”,¹ the influence of ECHA and what it does on a day-to-day basis puts it at the very heart of modern chemicals regulation. Aside from REACH, the Agency is now also the responsible regulator under the Biocides Regulation,² the CLP Regulation³ and the Prior Informed Consent Regulation.⁴ This Chapter, however, is concerned solely with ECHA’s role in relation to REACH. It begins with a review of ECHA’s mission before turning to exploration of the Agency’s structure and financing. The Chapter then considers how guidance is developed and disseminated via ECHA. Guidance produced in relation to REACH is expansive. The later Chapters of this thesis show how that guidance amplifies, standardises, translates and extrapolates the text of the Regulation. This Chapter sets out how that guidance comes into being. It also considers judicial and non-judicial accountability mechanisms, both for ECHA in general and its guidance in particular. In so doing, it explores some of the implications for law of changes in governance.

In their 2012 review of REACH, the Commission described the Agency as follows:

“ECHA is a decentralised agency: it draws up opinions so that the Commission can enact legislative proposals (e.g. in the restrictions area) or take specific decisions (e.g. granting or refusing authorisations). It has, in addition, own decision-making powers allowing it to adopt individual decisions needing a defined technical expertise, under clearly and precisely defined conditions and without discretionary power (e.g. in the

¹ Recital 15

² Council Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products [2012] OJ L 167/1

³ Council Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures [2008] OJ L 353/1

⁴ Council Regulation (EU) 649/2012 concerning the export and import of hazardous chemicals [2012] OJ L 201/60

area of evaluation); however, it is not allowed to adopt legislative measures of general application.”⁵

It is probably worth noting that ECHA is not the only EU regulatory agency with oversight of chemicals. Others (such as the European Environment Agency and the European Food Standards Agency) also play a role. In the rise of EU regulatory agencies with competencies for chemicals, we see devolution of State power outwards.⁶ Interestingly, different agencies have been granted different competencies: some, like the European Environment Agency, have merely advisory functions; others, like the European Food Standards Agency, can issue non-binding directions; and there are those, like ECHA, that can create orders with binding effect.⁷ There are then, in addition, a whole host of regulators with responsibility for chemicals control in the 28 Member States. At the EU level, this creates a regulatory landscape with varying topology. Since 2001, there has been a proliferation of EU agencies as part of an effort to free the Commission from certain regulatory and/or executive tasks that are predominantly of a technical or scientific nature. Interestingly, ECHA is one of only four EU agencies with the ability to take decisions that are binding on third parties.⁸

ECHA’s Mission

Titling itself as the “driving force” among regulators working on REACH, the Agency puts its mission as follows,

“ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.”⁹

⁵ Commission, ‘Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH: Staff Working Document ‘(SWD (2013) 25 final), 79 (hereafter, the ‘2012 REACH Review Report’)

⁶ On this, see: Veerle Heyvaert, ‘Regulating Chemical Risk: REACH in a Global Governance Perspective’ in Johan Eriksson, Michael Gilek and Christina Rudén (eds) *Regulating Chemical Risks* (Springer 2010) 223

⁷ Barbara Stibernitz, ‘A Brief Comment on Science Based Risk Regulation Within the European Union’ (2012) 1 *European Journal of Risk Regulation* 86

⁸ Sami Andoura and Timmerman, ‘Governance of the EU: The Reform Debate on European Agencies Reignited’ (European Policy Institutes Network Working Paper, 2008), 12

⁹ See: <<http://echa.europa.eu/web/guest/about-us/who-we-are/mission>> accessed 10 August 2014

What is noteworthy here is the explicit reference to ‘companies’ and the lack of explicit reference to other, non-private sector, stakeholders. That being said, the Agency’s five values do reference the public and state that ECHA will be: transparent; independent; trustworthy; efficient; and “committed to well being”.¹⁰ These map somewhat imperfectly with Recital 95 to the Regulation which states that confidence in ECHA will only be secured if it is independent, transparent and efficient, with high scientific, technical and regulatory capacities. The difficulties in sourcing the right scientific, technical and regulatory expertise for ECHA are well known. Much of this, it seems, comes down to location. Here, the Commission comments that:

“The location of ECHA in Helsinki is reported to pose a particular challenge for staffing. In spite of considerable, and highly appreciated, efforts of Finland and the City of Helsinki to create a welcoming environment for staff members and their families, promising candidates have been reported to turn down offers of employment for reasons linked to the climatic conditions, the remoteness of the location compared to the rest of the EU, and difficulties for spouses and partners to find attractive employment.”¹¹

ECHA plans its activities through three-year multi-annual work programmes (MAWPs) and annual work programmes (WPs)¹². ECHA’s ‘general reports’¹³ provide accounts of the Agency’s progress in a given year and every five years ECHA is obliged to produce a report on the operation of REACH. The first of these was published in 2012.¹⁴ Its findings are discussed throughout this Chapter and elsewhere in this thesis.

ECHA’s Structure

On a structural level, REACH envisages three committees working as part of ECHA: a Member State Committee (which has the task of attempting to achieve agreement

¹⁰ See: <<http://echa.europa.eu/about-us/who-we-are/values>> accessed 10 August 2014

¹¹ 2012 REACH Review Report (n 5), 82

¹² See: <<http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports>> accessed 10 August 2014

¹³ *ibid*

¹⁴ European Chemicals Agency, ‘The Operation of REACH and CLP’ (Helsinki, 2011) (hereafter, the ‘ECHA 2011 Report’)

among Member States where a harmonised approach under REACH is required); a Committee for Risk Assessment; and a Committee for Socio-economic Analysis (both of which issue scientific opinions in certain contexts)¹⁵. In addition, there is a Management Board, a Secretariat¹⁶, a Board of Appeal and a Forum for Exchange of Information on Enforcement (the “Forum”).¹⁷

In the start-up phase of REACH (mid 2007), the initial team at ECHA consisted of 38 seconded staff from the Commission. The Agency’s Secretariat currently comprises more than 500 staff members, divided over seven Directorates and into twenty three ‘units’.¹⁸ This diffusion of personnel has led to an acknowledged lack of coherency within the Agency and is something ECHA has identified as an area for improvement.¹⁹ The range of work undertaken by the Secretariat is vast and is, as the Commission has noted, “not purely administrative but goes deeply into technical-scientific issues; in that sense the name “Secretariat” may be a little limitative”.²⁰ Looking to the future, the work of the Secretariat will broaden, as it is granted additional responsibilities under the new Biocidal Products Regulation,²¹ and under the Prior Informed Consent Regulation (which concerns the import and export of dangerous chemicals).²² One of the key units within the Secretariat is the Helpdesk which, as the name would suggest, exists to provide advice on compliance with the Regulation. By March 2011, the Helpdesk had received and responded to more than 30,000 queries.²³ The annual reports produced by ECHA do not detail from whom the queries originated and such may be important to understanding the interpretative role played by the Agency.

¹⁵ Recitals 102 and 103; Articles 76(1)(c), (d) and (e).

¹⁶ As will be recalled from Chapter 3, the Secretariat has responsibility for supporting the Management Board in administrative and certain technical matters. Recital 98 details that “In the interests of efficiency, the staff of the Agency Secretariat should perform essentially technical-administrative and scientific tasks without calling on the scientific and technical resources of the Member States.”

¹⁷ Articles 76(1)(f), (g) and (h)

¹⁸ <<http://echa.europa.eu/web/guest/about-us/who-we-are/organisation>> accessed 10 August 2014

¹⁹ ECHA 2011 Report (n 14) 80-81

²⁰ 2012 REACH Review Report (n 5) 82

²¹ Biocidal Products Regulation (n 3)

²² Prior Informed Consent Regulation (n 5)

²³ ECHA 2011 Report (n 14) 51

Management of ECHA

All EU agencies have a main governing body with a supervisory role, general responsibility for budgetary and planning matters as well as for reporting the agency's activities to the EU institutions. In ECHA, the Management Board (the "Board") is led by an Executive Director²⁴ and comprises 28 Member State representatives (one from each State),²⁵ up to 6 representatives appointed by the Commission and 2 independent persons appointed by the Parliament.²⁶ The tasks of the Board include the adoption of the work programme, an annual report and other strategic documents as well as the adoption of ECHA's budget and the delivery of an opinion on the final accounts. The Board also appoints the Executive Director, the Board of Appeal and the members of the Committee for Risk Assessment and the Committee for Socio-economic Analysis, and may invite stakeholders to Committee meetings.

The current Executive Director of ECHA is Geert Dancet, a Commission employee from 1986 – 2007 (who headed the REACH unit of DG Enterprise). He is now in his second, and final, term of office at the Agency.²⁷ During the initial selection process for the Executive Director of REACH, the Commission put forward only two candidates for the Board to consider (including Mr Dancet). This led to an official complaint being made to the Ombudsman, which was upheld.²⁸ The Ombudsman found that it was, "impossible to verify that the Commission did not unduly and arbitrarily restrict the range of candidates for the post of ECHA Executive Director and did not abuse its discretion in the matter".²⁹ This course of action by the Commission is interesting in that it suggests that the Commission saw ECHA as crucial in completing the chemicals regime that the Commission had first put forward (and, as a consequence, that the appointment of its Executive Director was also crucial).

²⁴ Articles 76(1)(a) and (b)

²⁵ From the signing of the Accession Treaty with Croatia, the Management Board decided to grant Croatia observer status and to invite a representative of Croatia to attend the meetings of the Management Board and the Committees.

²⁶ The list of current (October 2013) Board members can be found here:

<http://echa.europa.eu/about/organisation/management_board/management_board_members_en.asp> accessed 10 August 2014

²⁷ Article 84(2)

²⁸ 2012 REACH Review Report (n 5) 81

²⁹ *ibid*

As part of the 2012 review of REACH, PricewaterhouseCoopers ('PwC') had been asked by the Commission to produce a report on ECHA.³⁰ One of their recommendations was that ECHA's Board would be more efficient with fewer members (in particular, via a reduction in the number of Member State representatives).³¹ This echoes other work which has criticised full Member State representation in EU agency boards as unnecessary, costly and ineffective.³² Despite these criticisms, the Commission concluded in the 2012 review of REACH that it, "sees no need to change the composition of the Management Board."³³ The following two sections consider ECHA's Forum on Enforcement and the ECHA Board of Appeal. Both have considerable input into the soft law framework that underpins REACH.

The Forum on Enforcement

ECHA's Forum on Enforcement, which coordinates a network of Member State authorities responsible for enforcement, is unique among EU agencies. The Commission has supported the need for its existence in the following terms,

"The increased responsibility of operators for the safe use of chemicals, a shift in mindset, that is at the very core of REACH, meant that enforcement of the legislation needed to be strengthened at EU level. In this light it was considered appropriate to provide a more formal framework for the co-operation among enforcement authorities which had emerged under the previous chemicals legislation."³⁴

Article 77(4) of REACH sets out that the tasks for which the Forum is responsible.

These are:

"(a) spreading good practice and highlighting problems at Community level;

³⁰ PwC, 'Review of the European Chemicals Agency' (Report to the European Commission, March 2012) – see: < http://ec.europa.eu/enterprise/dg/files/evaluation/201203-final-report-echa_en.pdf> accessed 10 August 2014

³¹ *ibid*, 45

³² Ramboll Management, 'Evaluation of the EU decentralised agencies in 2009' (Report for the European Commission, December 2009)

³³ 2012 REACH Review Report (n 5) 81

³⁴ 2012 REACH Review Report (n 5) 83. This largely echoes Recital 105 to the Regulation.

- (b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;
- (c) coordinating exchange of inspectors;
- (d) identifying enforcement strategies, as well as best practice in enforcement;
- (e) developing working methods and tools of use to local inspectors;
- (f) developing an electronic information exchange procedure;
- (g) liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary; and
- (h) examining proposals for restrictions with a view to advising on enforceability.”

In terms of composition, the Forum has a representative from each Member State plus three members appointed by Iceland, Liechtenstein and Norway.³⁵ These representatives are in turn supported by the REACH competent authorities in their respective Member/EEA/EFTA States. The Forum can also co-opt experts to assist it, but has not chosen to do so thus far. To date, the Forum has created one ‘REF’ (REACH-EN-FORCE) project,³⁶ which looked to assess the compliance of manufacturers and importers of substances with the REACH obligations on the pre-registration and Safety Data Sheets. In total, 1,589 inspections were carried out during 2010 in the then 27 Member States.³⁷

The Forum has also published guidance for Member State competent authorities, which sets out, “guidelines, in the form of minimum criteria, to be applied as a common basis for the performance of REACH and CLP inspection activities within the Member States and EEA-EFTA States.”³⁸ ECHA says that this is, “consistent with some of the principle tasks of the Forum under Articles 76(1)(f) and 77(4) of REACH”.³⁹ However, and as detailed above, REACH says nothing about harmonised, minimum criteria for enforcement (even though such an approach is not new in the wider field of environmental law).⁴⁰ While issuing such criteria might be “consistent”

³⁵ For the full list of members, see: <<http://echa.europa.eu/web/guest/about-us/who-we-are/enforcement-forum/members-of-the-forum>> accessed 10 August 2014

³⁶ <<http://echa.europa.eu/about-us/who-we-are/enforcement-forum>> accessed 10 August 2014

³⁷ <http://echa.europa.eu/documents/10162/13585/ref-1_project_report_conclusions_en.pdf> accessed 10 August 2014

³⁸ See:

<http://echa.europa.eu/documents/10162/13577/mcri_minimum_criteria_reach_inspections_2011_en.pdf> accessed 10 August 2014

³⁹ *ibid*, 2

⁴⁰ Minimum criteria have already been set for environmental inspections under ‘Council Recommendation no. 2001/331/EC of 4 April 2001 providing for minimum criteria for environmental

with the tasks with which the Forum is furnished, there is arguably a lack of explicit grant of authority. This, it is suggested, is an example of the Forum translating Articles 76(1)(f) and 77(4) of REACH to make the Regulation work better in practice. Later Chapters show similar translation by ECHA, and the significance of this guidance function is discussed in Chapter 9.

One of the few matters to be given ‘very high’ priority in the Forum’s 2011-2013 Work Programme is the, “clarification of the interlinks between ECHA, Competent Authorities and MS enforcing authorities”. This lack of clarity in and further matters relating to enforcement under REACH are discussed in Chapter 8.

The Board of Appeal

The Board of Appeal is responsible for deciding on appeals lodged against decisions of the Agency listed in Article 91 of REACH. The Commission argues that the Board of Appeal, “provides a possibility of legal redress which is quicker, less formal and less expensive than an action to the Court of Justice of the European Union.”⁴¹

The ECHA Board of Appeal comprises three members: a Chairman and two others⁴², each appointed by the Management Board⁴³. The three members (and their “alternates”, who represent the members of the Board of Appeal in their absence) must have appropriate technical and/or legal qualifications.⁴⁴ The matters for which an appeal may be brought before the Board are somewhat limited.⁴⁵ Article 91 details that an appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 51 of REACH. Broadly, what this means is that the Board of Appeal may hear appeals in relation to

inspections’, as elaborated by the European Union Network for the Implementation and Enforcement of Environmental Law (IMPEL)

⁴¹ 2012 REACH Review Report (n 5) 84

⁴² Article 89(1)

⁴³ Article 89(3)

⁴⁴ Article 1 of Commission Regulation (EC) No 1238/2007 of 23 October 2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency. For a list of current members of the Board of Appeal, see: <<http://echa.europa.eu/about-us/who-we-are/board-of-appeal/the-board-of-appeal/the-list-of-the-members-of-the-board-of-appeal-and-the-alternate-additional-members>> accessed 10 August 2014

⁴⁵ For all other decisions of ECHA, an action may lie before the General Court (formerly the Court of First Instance) or the Court of Justice of the European Union (formerly the European Court of Justice) (Article 94(1))

the following decisions taken by ECHA: Exemptions from the general obligation to register for product and process orientated research and development; Rejections of registrations; Sharing of existing data in the case of registered substances; Sharing of data involving tests; Examination of testing proposals; Compliance check of registrations; and Substance evaluation.

Those with standing to appeal comprise the usual suspects of EU law:⁴⁶ any natural or legal persons to whom a decision is addressed; and those persons to whom a decision is or direct and individual concern (even though not addressed to them).⁴⁷ Appeals must be brought within three months⁴⁸ and decisions of the Board of Appeal are subject to challenge before the General Court (formerly, the Court of First Instance).⁴⁹ The Board has published guidance in the form of Practice Directions to assist applicants with their appeals.⁵⁰

The Board of Appeal sits within ECHA's organisational structure, is located inside the Agency's offices in Helsinki and yet deals with appeals against ECHA's decisions. As the Commission has noted, this "poses specific challenges".⁵¹ Despite this, stakeholders interviewed as part of PwC's review of REACH were confident that the Board of Appeal is independent.⁵² The real proof of the pudding will likely come as the workload of the Board increases. As of 10 August 2014, only 39 appeals had been lodged since the creation of the Agency in 2007.⁵³ While the number of appeals is small, it should be remembered that ECHA has made relatively few appealable decisions to date (see Chapter 6 for a review of Evaluation under REACH) and that the Board of Appeal should find its workload increasing over time.

⁴⁶ On the area of the jurisdiction of the European Courts and the question of standing more generally, see Part IV of: Alan Dashwood, Michael Dougan, Barry Rodger, Eleanor Spaventa and Derrick Wyatt, *Wyatt & Dashwood's European Union Law* (6th edn, Hart 2011)

⁴⁷ Article 92(1)

⁴⁸ Article 92(2)

⁴⁹ Article 94(1)

⁵⁰ <http://echa.europa.eu/documents/10162/13573/appeals_practice_directions_en.pdf> accessed 10 August 2014

⁵¹ 2012 REACH Review Report (n 5) 84

⁵² PwC (n 24) 31

⁵³ <<http://echa.europa.eu/about-us/who-we-are/board-of-appeal/announcements>> accessed 10 August 2014

ECHA Committees

As noted above, REACH envisages three committees working as part of ECHA: a Member State Committee ('MSC'); a Committee for Risk Assessment ('RAC'); and a Committee for Socio-economic Analysis ('SEAC').⁵⁴ In terms of composition, members of the RAC and SEAC are appointed by the Management Board, upon nomination of candidates with relevant experience by Member States. At least one, and no more than two members nominated by each Member State can be appointed in this way: the RAC currently has 41 members⁵⁵; and the SEAC 30 members⁵⁶. Members of the MSC are appointed directly by the Member States, each appointing one member.⁵⁷

Committees for Risk Assessment and Socio-Economic Analysis

The main obligations of the RAC include opinions on authorisation applications and on proposals for restrictions.⁵⁸ The RAC also has obligations under the Classification, Labelling and Packaging Regulation (commonly known as 'CLP').⁵⁹ What this means, on a practical level, is that the Committee is under a quickly increasing workload and has been chastised by the Commission for not working efficiently⁶⁰. The RAC has also come under criticism for failing to be transparent on how stakeholders can become involved in its work.⁶¹

Like the RAC, the main responsibilities of the SEAC also include opinions on authorisation applications and on proposals for restrictions. It too has been encouraged to become more efficient as its workload increases.⁶² The roles and work of the RAC and SEA are considered in more depth in Chapter 7 on Authorisation and Restriction.

⁵⁴ Recitals 102 and 103; Articles 76(1)(c), (d) and (e)

⁵⁵ <<http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment>> accessed 10 August 2014

⁵⁶ <<http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis>> accessed 10 August 2014

⁵⁷ <<http://echa.europa.eu/about-us/who-we-are/member-state-committee>> accessed 10 August 2014

⁵⁸ Article 76(1)(a)

⁵⁹ CLP (n 4)

⁶⁰ 2012 REACH Review Report (n 5) 87

⁶¹ 2012 REACH Review Report (n 5) 88

⁶² *ibid*

Member State Committee

The MSC is different. As the Commission has observed, it, “falls nearly completely outside the classic committee paradigm.”⁶³ In terms of its work, the MSC is responsible for resolving divergences of opinions among Member States on proposals for the identification of Substances of Very High Concern. The Committee also provides opinions on ECHA's draft recommendations for the authorisation list (the so-called ‘Candidate List’)⁶⁴ and draft Community Rolling Action Plan for the substance evaluation process. If an agreement is not reached within the MSC, the matter is then referred to the Commission for decision-making.⁶⁵ In this context, the Commission has commented that,

“This referral to the Commission for decision is an illustration of the extraordinary role and nature of the MSC which leads MSC members to some, perhaps too large, extent to engage in policy discussions rather than scientific-technical discussions.”⁶⁶

The functioning of the MSC to date thus suggests that the parameters of REACH may open to negotiation. While the MSC exists to facilitate consensus building, there have also been reports of difficulty in getting agreement among the committee members as to the inclusions of SVHCs onto the Candidate List.⁶⁷ The tone of the Commission’s 2012 review of REACH is very much that the MSC is an oddity and lacks efficiency.⁶⁸ Despite this, and despite the lack of clarity on the accountability of MSC representatives, the Commission did not suggest amending REACH to alter the composition or role of the MSC.

Directors’ Contact Group

Established in 2010, the Directors' Contact Group (DCG) provides a platform for the exchange of views between the European Commission, ECHA and nine industry

⁶³ 2012 REACH Review Report (n 5) 86

⁶⁴ On which, see Chapter 7 on Authorisation and Restriction

⁶⁵ Recital 67 and Articles 45(3), 53(7) and 59(9)

⁶⁶ 2012 REACH Review Report (n 5) 89

⁶⁷ *ibid*

⁶⁸ 2012 REACH Review Report (n 5) 88-89

associations.⁶⁹ In essence, the DCG is a problem solving group which seeks to capitalise on industry expertise to find solutions to issues which arise during the operation of REACH. This body was not envisaged, and is not referred to, in the Regulation. This is telling. ECHA comments that,

“Under its initial mandate, the DCG found solutions to 28 issues of concern for industry relating to the first REACH Registration deadline of 30 November 2010. These solutions were shared with the Member State Competent Authorities through the CARACAL advisory body and with the EU/EEA Enforcement Authorities through the Forum for Exchange of Information on Enforcement.”⁷⁰

The issues that the DCG has dealt with to date have been technical or practical – for example, what should be done where a company splits in two and one of new entities has not undergone pre-registration.⁷¹ While the mandate of the group says that it is “informal” and that its role is to “monitor” the operation of REACH and “promote best practice”, it is clear that ECHA expects the guidance produced by the DCG to be followed.⁷² Interestingly, the DCG refers to its solutions as “recommendations” rather than guidance. Given the practical effect is the same, the distinction does not seem to make much, if any, difference.

Stakeholder Engagement

ECHA comments that, “All organisations and individuals interested in or affected by the chemicals regulations are considered as ECHA's stakeholders and are welcome to participate in the Agency's work.”⁷³ While the sincerity of this statement is not in

⁶⁹ The nine are: Cefic, Eurométaux, REACH Alliance, CONCAWE, FECC, UEAPME; Orgalime, DUCC and CheMI Platform.

⁷⁰ <<http://echa.europa.eu/about-us/partners-and-networks/directors-contact-group>> accessed 10 August 2014

⁷¹ <<http://echa.europa.eu/web/guest/about-us/partners-and-networks/directors-contact-group/dcg-issues>> accessed 10 August 2014

⁷² <http://echa.europa.eu/documents/10162/13559/rrd-56-10_mandate_dcg10_final_en.pdf> accessed 10 August 2014

⁷³ <<http://echa.europa.eu/about-us/partners-and-networks/stakeholders>> accessed 10 August 2014

doubt, and ECHA organises various public engagement events,⁷⁴ the reality is that a very small number (of largely industry based organisations) are actively targeted by ECHA and engage with the operation of the Regulation. ECHA works particularly closely with what it terms “Accredited Stakeholder Organisations” (‘ASOs’), who represent differing fields of competence at the EU level. Looking at the list of ASOs,⁷⁵ the vast majority are industry representative bodies: only 7 out of the 69 accredited ASOs represent civil society. In their 2012 review of REACH, the Commission noted the lack of paucity of engagement with REACH aside from those directly within the Regulation’s purview (i.e. industry).⁷⁶ This is also seen (and discussed below) in the context of stakeholder engagement in the generation of REACH guidance.

The Financing of ECHA

ECHA is financed partly by fees paid by natural or legal persons under REACH (i.e. the fees paid for registration) and partly by the general budget of the European Communities.⁷⁷ It is also open to Member States to make “voluntary contributions” to the Agency.⁷⁸ None have done this so far. The original EU subsidy was a balancing subsidy designed to cover the start-up of ECHA (when no or insufficient fees were coming in) as well as any income gaps caused by fee income fluctuations between registration peaks. Since 2010, ECHA has been fully financed by the fees paid for registration.⁷⁹ In 2012, while the Agency continued to be fully self-financed for its activities under the REACH, it received its first EU subsidies for performing its tasks under the Biocidal Products and PIC Regulations.⁸⁰ ECHA’s expenditure has risen from EUR 13m in 2007,⁸¹ to EUR 95m in 2012.⁸²

⁷⁴ Including workshops during the year together with an annual Stakeholders’ Day which is held in Helsinki and also broadcast over the Internet. See: <http://echa.europa.eu/view-article/-/journal_content/56_INSTANCE_0Jp4/5921bbb3-3f0c-4db9-97b9-c65aa185a508> accessed 10 August 2014

⁷⁵ <<http://echa.europa.eu/web/guest/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations>> accessed 10 August 2014

⁷⁶ 2012 REACH Review Report (n 5)

⁷⁷ Recital 107, Article 96(1)(a) and (b)

⁷⁸ Article 96(1)(c)

⁷⁹ 2012 REACH Review Report (n 5) 90

⁸⁰ *ibid*, 11

⁸¹ ECHA, ‘General Report 2007’ (Helsinki, 2007) 8

⁸² ECHA, ‘General Report 2012’ (Helsinki, 2012) 10

Guidance produced by ECHA

REACH is vast and the norms in the Regulation take a variety of forms: some are prescriptive and detailed; others are bare framework commands without any underlying substance in the Regulation (e.g. create a SIEF). Article 77(2) details that one of the tasks of ECHA's Secretariat is to,

“... (g) provide technical and scientific guidance and tools where appropriate for the operation of this Regulation...;

h) provide technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the helpdesks established by Member States...; [and]

(i) provide guidance to stakeholders including Member State competent authorities on communication to the public of information on the risks and safe use of substances...”

This mandate is wide and non-specific. However, the Regulation then also details a small number specific instances where the Agency is obliged to produce guidance: for example, cost sharing guidance for SIEFs;⁸³ and applications for authorisation which require socio economic analysis.⁸⁴ Since 2003, more than one million words of official guidance have been produced on REACH. ECHA's Document Library (the central repository for publicly available ECHA documents)⁸⁵ contains 482 separate 'support' documents. This is made up of: (a) 138 guidance documents; (b) 34 Helpdesk documents; (c) 185 documents relating to IT Tools; and (d) 67 Manuals.

The guidance produced and disseminated by ECHA takes a variety of forms. The table below details the title of the guidance format, their nature, how many of them have been produced and the length of the documents.

⁸³ Article 27(1)

⁸⁴ Annex XVI

⁸⁵ <<http://echa.europa.eu/web/guest/support/documents-library>> accessed 10 August 2014

Table 5.1 – ECHA Guidance Documents

Name	Nature of documents	Length
Guidance ⁸⁶	<p>With the core guidance documents, ECHA says that, “These documents have been developed with the participation of many stakeholders: Industry, Member States and NGOs. The objective of these documents is to facilitate the implementation of the legislation in ECHA's remit by describing good practice on how to fulfil obligations in the Regulation.”⁸⁷</p> <p>It is interesting to note the lack of reference above by ECHA to: (a) the public; and (b) other branches of the EU (e.g. Commission and Parliament).</p>	<p>These 21 documents contain more than one million words of guidance. One of the core guidance documents is almost three times the length of this thesis. The specifics of each of the core guidance are set out in Appendix 2 to this thesis.</p>
‘Guidance in a Nutshell’	<p>ECHA comments that they have produced, “a series of shortened versions of the REACH Guidance Documents in order to make the corresponding Guidance Documents published by the Agency more accessible for industry.”⁸⁸</p>	<p>The 5 Nutshell documents vary from 2,500 words in length to over 9,000 words; between 10 and 20 pages long. For the longer of these documents, “nutshell” is perhaps a misnomer.</p>
‘Guidance Factsheets’	<p>These provide a “structured overview” of the guidance documents and include a summary of the key aspects, bibliographic information and other references. The core guidance documents are so complex that they require their own guidance/explanatory maps.</p>	<p>Each of the 10 Guidance Factsheets is 4-5 pages long.</p>
‘Practical Guides’	<p>These provide “practical information” on REACH and are essentially ‘how to’ guides (e.g. how to avoid unnecessary animal testing; how to report in vitro data). These are highly procedural</p>	<p>15 Practical Guides; each 20-30 pages each.</p>

⁸⁶ ECHA simply calls these documents ‘guidance’. To distinguish them from the various other forms of guidance, I refer to them as ‘core guidance’ documents.

⁸⁷ <<http://echa.europa.eu/support/guidance>> accessed 10 August 2014

⁸⁸ <<http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/guidance-in-a-nutshell>> accessed 10 August 2014

	(and, for example, show screen shots of various forms to be completed as part of Registration).	
‘Formats’	These are templates of certain of the reports to be submitted to ECHA (e.g. Chemical Safety Report or Annex XV dossier on Restriction). Linked with these, and in addition to the Practical Guides, ECHA also publishes Practical Examples, which give illustrative examples of how completed chemical safety assessments and exposure scenarios should look. ⁸⁹	7 Formats. Varying length. These are, in effect, shells to be completed by registrants and Member State Competent Authorities.

In addition to the guidance documents detailed above there are, as of 10 August 2014, answers to 889 separate FAQs set out on the ECHA website.⁹⁰ The Agency accepts that some of its guidance is dense and complex and is working on making the documents more accessible and, where possible, more simple.⁹¹ ECHA labels everything save for the core guidance documents as “quasi guidance”, with the intent that these are “in simple terms” and particularly intended for SMEs.⁹² There is then an implicit hierarchy of norms in the guidance ECHA produces. The Agency sees its guidance as living documents and comments that, “Guidance reflects the ‘state-of-the-art’ in the practical implementation of the legislation.”⁹³

Guidance History

The history of ECHA’s guidance documents is rooted in the REACH Implementation Projects (‘RIPs’). Orchestrated by the Commission and beginning in 2003, the RIPs were designed, “to ensure that all stakeholders, especially industry and public authorities, are adequately prepared for the practical application of the new system.”⁹⁴ The day-to-day management of the RIPs was conducted by the European Chemicals Bureau (‘ECB’) which, prior to REACH, was the focal point for the data and assessment procedure on dangerous chemicals within the European Union.

⁸⁹ <<http://echa.europa.eu/web/guest/support/practical-examples-of-chemical-safety-reports>> accessed 10 August 2014

⁹⁰ <<http://echa.europa.eu/support/qas-support/search-qas>> accessed 10 August 2014

⁹¹ ECHA 2011 Report (n 14) 46

⁹² *ibid*

⁹³ *ibid*

⁹⁴ <<http://ec.europa.eu/environment/chemicals/reach/preparing/>> accessed 10 August 2014

In 2008 the ECB completed its mandate and ceased to exist. Some of its activities were taken over by ECHA; others remained within the Joint Research Centre's Institute for Health & Consumer Protection. The ECB website no longer exists. What this means, on a practical level, is that the information related to RIPs 3 and 4 (which produced the 15 initial REACH guidance documents for industry and Member State regulators) is no longer accessible.⁹⁵ Nor is the website cached somewhere else for easy access.⁹⁶ The guidance itself remains (housed on ECHA's website) but there is no public information on the development of the RIPs, the stakeholders engaged, the challenges encountered etc. This lack of publicly available data has been confirmed by the Health & Safety Executive (the main regulator for REACH in England & Wales).⁹⁷ A presentation by an ECB official in 2006 details that the initial guidance documents produced under the RIPs were created via an open call for tenders, with working drafts discussed by Stakeholder Expert Groups and input from Member States, NGOs, the Commission and industry.⁹⁸ All of the guidance documents produced under RIPs 3 and 4 were designed to be completed by the end of 2007.

Guidance Development and Stakeholder Engagement

A Guidance Consultation Procedure was first adopted by ECHA's Management Board in 2008, with full implementation of the procedures and workflows for developing and updating guidance occurring in 2009.⁹⁹ ECHA's aim with the development and review of guidance is to build consensus between various actors. This, however, is not always possible. The 2008 Guidance Consultation Procedure was said to have led to, "protracted discussions on scientific, technical or policy issues which caused delays."¹⁰⁰ As a result, ECHA implemented a new Consultation Procedure on Guidance in 2011, which allows the Agency to, "finalise guidance on the basis of majority views if full consensus cannot be achieved."¹⁰¹ This new

⁹⁵ See the non-functioning <<http://ecb.jrc.it/reach-it/>> accessed 10 August 2014

⁹⁶ See: <http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/where-do-i-find-the-former-european-chemicals-bureau-web-content> accessed 10 August 2014

⁹⁷ Email to the author of 26 July 2013. Copy on file.

⁹⁸ <<http://reach.chemnet.com/upload/0702051106531456.pdf>> accessed 10 August 2014

⁹⁹ ECHA, 'General Report 2009' (Helsinki, 2009) section 1.5

¹⁰⁰ ECHA 2011 Report (n 14) 47

¹⁰¹ *ibid*

approach, and ECHA's guidance more generally, raise interesting questions about legislative mandate, agency power, transparency and accountability. These are discussed in more detail in Chapter 9.

ECHA's Secretariat collects data on difficulties with the guidance that the Agency has produced. This data comes in via helpdesks (ECHA's own and those of the Member States), from ECHA's committees (the RAC, SEAC and MSC), the Commission and Member State competent authorities.¹⁰² Once issues with guidance are identified, there are four possible actions: (a) a corrigendum (which is a simple editorial change or correction); (b) an amendment (which changes the substance of one part of the guidance); (c) a revision (a more whole scale review of the guidance); or (d) the issuing of a wholly new guidance document.¹⁰³ Where the Secretariat realise that "comprehensive work is required", a formal consultation process begins. This starts with the Commission (which sees a first draft of any changes) and then broadens to include a Partner Expert Group ('PEG'), experts from ECHA's committees and a final (re)consultation of the Commission and Member State competent authorities.¹⁰⁴ The 2011 Consultation Procedure on Guidance details that the Secretariat decides whom to consult and on the time frames given for consultation.¹⁰⁵ Much of the consultation is 'closed' in that it involves experts "whose nominations have been received by a specified deadline"¹⁰⁶ and who are then formed into PEGs.¹⁰⁷ The ECHA website does not detail lists of experts within PEGs formed as part of previous consultations on guidance. Only in limited situations (for example, entirely new guidance) will ECHA engage in full public consultation. This goes to the legitimacy of ECHA's guidance, is potentially of concern and is discussed in more depth in Chapter 9.

On occasion, updated guidance has been intentionally delayed to allow for stability in the run up to registration deadlines.¹⁰⁸ At present, updated guidance is published at three specific times during the year, "to enable industry to better plan for changes."¹⁰⁹

¹⁰² ECHA, '(Revised) Consultation Procedure on Guidance' (MB/14/2011 final, 2011) 2

¹⁰³ *ibid*, 3

¹⁰⁴ ECHA (n 103) 4

¹⁰⁵ *ibid*

¹⁰⁶ It is not clear what this deadline is or how it is disseminated.

¹⁰⁷ ECHA (n 103) 5

¹⁰⁸ ECHA, 'General Report 2010' (Helsinki, 2010) 19

¹⁰⁹ ECHA, 'General Report 2011' (Helsinki, 2011) 28

The Agency comments that stakeholder engagement in the guidance updating process is important: (a) to reduce possibility of errors; and (b) to get, as ECHA terms it, “buy in” from the various actors.¹¹⁰ ECHA’s 2011 review of REACH details that, between 2006 and 2011, the Agency published 71 guidance documents, undertook 30 consultations on guidance with Member State competent authorities and consulted 254 experts as part of the PEG.¹¹¹

ECHA Guidance and Accountability

With the expansion in new forms of governance (discussed in Chapter 2) come concerns about the extent to which they are legitimate and/or fit within existing notions of accountability. This section begins by looking at the formal, institutional accountability of ECHA. It then turns to a more in depth discussion of the role of the courts as an accountability mechanism, both generally in the context of soft law and more specifically in the context of the post legislative shaping of REACH via ECHA’s guidance.

ECHA Accountability

As was set out in Chapter 2 and earlier in this Chapter, the European Chemicals Agency sits at the heart of REACH. It has the power to take decisions that are binding on third parties without consulting the Commission or Member States and is one of a handful of EU agencies with such independence.¹¹² By way of contrast, although the European Food Safety Authority is a scientific body charged with risk assessment in relation to foodstuffs, it is made clear that questions of risk management fall to the European Commission.¹¹³ The discretion granted to ECHA as regards the day-to-day operation of REACH is wide. Despite this, there are a number of mechanisms which

¹¹⁰ ECHA 2011 Report (n 14) 46

¹¹¹ *ibid*

¹¹² Sami Andoura and Peter Timmerman, ‘Governance of the EU: The Reform Debate on European Agencies Reignited’ (European Policy Institutes Network Working Paper 2008), 12 - see: <http://www.ceps.eu/book/governance-eu-reform-debate-european-agencies-reignited> accessed 10 August 2014

¹¹³ Terry Marsden, Robert Lee, Andrew Flynn and Samartha Thankappan, *Beyond the Food Crisis: the New Regulation and Governance of Food* (Routledge 2010) Chapter 5

have the potential to act as a check and/or balance on the exercise of the Agency's functions (including, but not limited to, the creation of guidance).

Formal accountability of ECHA is structured in a variety of ways, many of which are common to other EU agencies.¹¹⁴ The first of these is Member State, Commission and Parliament participation in ECHA's Management Board; the second is the influence of the Member State Committee during Evaluation and Authorisation (discussed in brief in Chapter 3, and in more depth in Chapters 6 and 7); and the third is via the Article 117 reporting obligations on the Agency (annual reports and a quinquennial review of REACH; also discussed in Chapter 3). As noted earlier in this Chapter, redress against decisions of ECHA may be found in the ECHA Board of Appeal, though the matters for which an appeal may be brought before the Board are somewhat limited.¹¹⁵ In the initial years of REACH, when ECHA was funded in part by EU subsidies, the European Parliament also had input to the Agency's budget.¹¹⁶ Finally, ECHA is one of only five agencies where the European Parliament has the possibility to invite the Executive Director for a hearing before his appointment.¹¹⁷ EU agencies more generally have been considered to be problematic because of their perceived lack of accountability.¹¹⁸ Here, there are broad tensions between, on the one hand, agency independence and the functional benefits of grouping together experts, and, on the other hand, anxiety about agencies exercising arbitrary power.¹¹⁹ The extent to which the above formal accountability mechanisms have impacted on the creation, amendment and promulgation of guidance by ECHA is uncertain. There is nothing in the public domain on this matter. Similarly, how the guidance produced by ECHA to underpin REACH is regarded by the Commission (or other EU bodies) is also not known. Despite the wealth of guidance relating to REACH, the Commission said little about ECHA's approach in its 2012 review of REACH. Aside from comments that ECHA's guidance should remain stable in the months preceding any registration deadline and a suggestion to target guidance for SMEs and in more EU

¹¹⁴ Ellen Vos, 'Making Informal International Law Accountable: Lessons from the EU' in Joost Pauwelyn, Ramses Wessel, and Jan Wouters (eds) *Informal International Lawmaking* (OUP 2012) 374

¹¹⁵ Article 91 For all other decisions of ECHA, an action may lie before the General Court (formerly the Court of First Instance) or the Court of Justice of the European Union (formerly the European Court of Justice) (Article 94(1))

¹¹⁶ Article 96

¹¹⁷ Andoura and Timmerman (n 112) 14

¹¹⁸ Madalina Busuioc, *European Agencies: Law and Practices of Accountability* (OUP 2013)

¹¹⁹ *ibid* 4

languages, the 2012 review is silent on the underlying rationale for the guidance and the methodology by which it is created and updated.¹²⁰ The Commission did, however, note that ECHA “is not allowed to adopt legislative measures of general application.”¹²¹ While this is true, the Agency does adopt other normative measures of general application in the form of guidance. Given the wealth of guidance produced by ECHA and the importance of this guidance in the shaping of the day-to-day operation of REACH, the Commission’s silence on this matter in the 2012 review is striking. Robust and informed monitoring is said to be one of the hallmarks of effective experimentalist governance systems.¹²² REACH contains the right sorts of monitoring obligations (ECHA annual reports, quinquennial Commission review etc), but, at least in the context of guidance making and promulgation, one might question whether the outputs (i.e. the reports themselves) are effective.

As was discussed in Chapter 2, soft post-legislative instruments are not a formally recognised branch of EU law. As such they lack legally binding force. However, these instruments are ‘soft law’ in that they established rules of conduct that have both, or may have both, practical and indirect legal effects.¹²³ The remainder of this Chapter considers the nature of these indirect legal effects and how soft law may be held to account by the judiciary. It unfolds in three parts: the first sets out the challenges in getting soft law, in general, and post legislative guidance, in particular, before the EU courts; part two looks at what the EU courts have said about soft law and how it may be used; and the final part then considers what the EU courts have said about the guidance produced under REACH.

However, before turning to the detail, it is worth briefly reviewing why it may be important to consider the role of the courts. As Scott and Sturm have observed, the

¹²⁰ Commission, ‘Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH: Staff Working Document (SWD (2013) 25 final) 27 – hereafter referred to as the ‘2012 REACH Review’

¹²¹ 2012 REACH Review, 79

¹²² Grainne de Burca, ‘New Governance and Experimentalism: An Introduction’ (2010) 2 *Wisconsin Law Review* 227, 235

¹²³ Linda Senden, ‘Soft Post Legislative Rulemaking: A Time for More Stringent Control’ (2013) 19(1) *European Law Journal*, 57, 62

courts offer up a “concrete site” where the tensions between law and new governance must be reconciled.¹²⁴ They argue that,

“in areas of normative uncertainty and complexity, courts prompt and create occasions for normatively motivated and accountable inquiry and remediation by actors involved in new governance processes.”¹²⁵

As such, they see courts “as catalysts”. In his review of soft instruments and the EU courts, Smismans similarly suggests that the “ideational repertoire” of soft law instruments may have an impact on EU jurisprudence.¹²⁶ The notions of catalysts and influence are appealing. However, there is an important empirical question, unanswered by Scott and Sturm, or by Smismans, as to the real world impact of the “signalling” that the courts do. As is seen below, and discussed by Scott in her later work on post legislative guidance,¹²⁷ while the number of cases concerning new governance (in any form) is sizeable, the number of cases on hybrid forms of governance, on soft law yoked with hard law, is small.

The Challenges in Adjudicating on Soft Law Instruments

Scott and Trubek have suggested that the EU courts have responded to shifts towards newer forms of governance in a variety of ways: thwarting experiments in new governance; ignoring those experiments; distorting new governance; or seriously engaging with it.¹²⁸ In later work, Hervey argues that the relationship between the EU courts and new governance operates along a spectrum ranging from, “mutual ignorance; through separation, either with hierarchy or in parallel; to hybrid forms of mutual transformation.”¹²⁹ It is at this furthest end of the spectrum that courts are,

¹²⁴ Joanne Scott and Susan Sturm, ‘Courts as Catalysts: Re-Thinking the Judicial Role in New Governance’ (New Modes of Governance Project, Paper LTF1a/D5h, 2007) 3

¹²⁵ *ibid*

¹²⁶ Stijn Smismans, ‘EU Law in the Lisbon governance architecture’ (2011) 18(4) *Journal of European Public Policy* 504, 518

¹²⁷ Joanne Scott, ‘In Legal Limbo: Post-Legislative Guidance as a Challenge for European Administrative Law’ (2011) 48 *Common Market Law Review* 329

¹²⁸ Joanne Scott and David M. Trubek, ‘Mind the Gap: Law and New Approaches to Governance in the EU’ (2002) 8 *European Law Journal* 1, 9ff

¹²⁹ Tamara Hervey, ‘Adjudicating in the Shadow of the Informal Settlement?: The Court of Justice of the European Union, “New Governance” and Social Welfare’ (2010) 63 *Current Legal Problems* 114, 138

“open to being persuaded as to the normative worth of diverse processes born of the diverse experiences of governance.”¹³⁰ Judicial review of soft law may occur either in direct action before the EU courts, under Article 263 TFEU, or via preliminary references made to the EU courts by Member State courts, under Article 267 TFEU. Article 263 TFEU details that the legislative and executive acts of EU institutions which create legal effects for third parties are amenable to judicial review, as are the acts of EU bodies and agencies that have the same effect. Article 263(4) TFEU sets out that natural and legal persons may, “institute proceedings against an act addressed to [them] or which is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures.”¹³¹

Article 267 allows the ECJ to give preliminary rulings on: (a) the interpretation of the Treaties; and (b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the EU. A national court may refer such questions to the ECJ if it considers that a decision on the question is necessary to enable it to give judgment. Where such questions are raised in cases before the final courts in any Member State, those courts are obliged to bring the matter to the attention of the ECJ. However, preliminary references happen infrequently for a variety of reasons.¹³² In the particular context of environment law preliminary references, “only a handful of questions are referred to the ECJ by the domestic judiciary.”¹³³ Despite this, of the 12 cases referred by the UK to the ECJ between 2007 and 2013, a third concerned REACH.¹³⁴ This is unsurprising, given that REACH entered into force in 2007 and was, as this thesis has shown, both new in many ways and highly contested.

In contrast to traditional hard law, soft law is less likely to be justiciable (for the reasons set out below) and thus there is a concern that a gap may open between

¹³⁰ Scott and Sturm (n 124) 591

¹³¹ This recent provision, introduced by the Lisbon Treaty, has been effective only since December 2009.

¹³² For an overview of why this is so, see: Veerle Heyvaert, Justine Thornton and Richard Drabble, ‘With reference to the environment: the preliminary reference procedure, environmental decisions and the domestic jury’ (2014) LQR 413

¹³³ *ibid* 413. Heyvaert et al set out that, “In 2010, 2011 and 2012, environmental cases made up respectively 6.8%, 4.5% and 4.7% of all preliminary references initiated, a percentage that is particularly modest when considering that, in the same period, environmental cases accounted for 25% of all infringement actions against Member States” (at 416).

¹³⁴ Heyvaert et al (n 132) 417

instruments created by bodies public which are and which are not amenable to judicial review. In this context, Scott argues that, “although the European Courts privilege substance over form in deciding which measures may be challenged, post legislative guidance will frequently escape the scrutiny of these courts.”¹³⁵ In 2002, Scott and Trubek argued that EU courts “have tended to ignore, or distort, new governance in order that new governance can be accommodated by the premises of a traditional, positivist concept of law.”¹³⁶ While there has been some progress (discussed below) this is largely still true today.

One issue is whether the soft law instrument is an act adopted by an institution of the EU.¹³⁷ If it is, then the act may be amenable to judicial review by the EU courts, but not otherwise. Importantly, and as a result of EU case law (now enshrined in the TFEU), acts adopted by EU agencies can be said to acts of an institution of the EU.¹³⁸ Thus, for present purposes, the core guidance produced by ECHA should, in theory, be justiciable. This is in contrast to other post legislative guidance issued, for example, in the area of emissions trading or water quality where either the authorship of the guidance is explicitly multiple (i.e. from members of a working group), or where the guidance (while seeking to elaborate on EU hard norms) is said to come from the joint action of the Member States.¹³⁹ What is of more concern in the context of REACH is whether the guidance produced by the Directors Contact Group (discussed earlier in this Chapter) would be amenable to review. While the DCG is not a part of ECHA, and is called “an informal platform”, its work is referred to by ECHA and the DCG’s outputs (communiqués and Terms of Work) are housed on the ECHA website.¹⁴⁰ Given this, and the privileging of substance over form,¹⁴¹ it is suggested that the DCG’s guidance should also be amenable to review.

¹³⁵ Scott (n 127) 329

¹³⁶ Scott and Trubek (n 128) 16

¹³⁷ Article 263 TFEU

¹³⁸ Case T-411/06 *Sogelma v EAR* [2008] ECR II-02771

¹³⁹ Scott (n 127) 338

¹⁴⁰ See: <<http://echa.europa.eu/about-us/partners-and-networks/directors-contact-group>> accessed 10 August 2014

¹⁴¹ Joined Cases C-181/91 and C-248/91 *European Parliament v Council* [1993] I-3685, paras 14 and 15

The question of authorship, for the majority of guidance produced under REACH, is not a significant bar to judicial review.¹⁴² Whether all of ECHA’s guidance formats are “acts...intended to produce legal effects” for the purposes of Article 263 TFEU is, however, another matter. As was set out earlier in this Chapter, ECHA labels everything bar its core guidance documents as “quasi guidance”, and each of the core guidance documents comes with a ‘Legal Notice’ that the content “does not constitute legal advice.” In *France v Commission*, the ECJ noted that,

“The Court has consistently held that an action for annulment is available in the case of all measures adopted by the institutions, whatever their nature or form, which are intended to have legal effects.”¹⁴³

In her review of case law in this area, Scott observes that Commission Communications, Commission Internal Instructions and a Commission Code of Conduct have all formed the subject matter of admissible actions for judicial review.¹⁴⁴ The extent to which this case law applies to ECHA’s guidance is discussed in more depth below (see the section headed, ‘EU Jurisprudence on Notices, Guidelines and Guidance’).

The Use of Soft Law by the EU Courts

The EU courts do refer to and, in more limited situations use, soft instruments, though they appear reluctant to employ certain terminology: the term ‘soft law’ only appears in 25 cases; “new governance” does not appear at all.¹⁴⁵ In *Germany v Council*, a recent case on the EU becoming a member of the Organisation of Vine and Wine, Advocate General Cruz Villalon accepted that there,

“acts known as ‘soft law’...[which] although not legally binding, nonetheless exhibit a degree of relevance through references made to

¹⁴² A separate, but related question goes to whether the significant amount of guidance produced by the private sector (industry groupings, NGOs etc) falls wholly outside any judicial accountability regime, despite the very significant behavioural shaping effects of those norms.

¹⁴³ Case C-57/95 *France v Commission* [1993] I-ECR 1627, para 7

¹⁴⁴ Scott (n 127) 339

¹⁴⁵ Curia search for these terms performed on 31 July 2014.

them, the reliance placed on them for the purposes of interpreting binding law or their practical effectiveness.”¹⁴⁶

However, he suggested that the catch-all of ‘soft law’ was “neither a legally relevant category of acts nor one that can be clearly circumscribed.”¹⁴⁷ While the latter is certainly true, and the limits of soft law may be porous, the former observation is disappointing. Given the widespread uses of soft law within the EU, they are relevant and are worthy of further exploration, in particular by the courts. This was arguably a missed opportunity. Earlier case law, while not referring explicitly to ‘soft law’, had already recognised that, “such rules of conduct, which are of general application, may produce legal effects.”¹⁴⁸ AG Sharpston, in a case concerning the EU Charter of Rights, had observed that,

“the Charter acquired the status of ‘soft’ law; that is to say, although its provisions were not directly applicable as part of EU law, they none the less were capable of producing legal effects – in many cases, far-reaching effects – within the Union.”¹⁴⁹

Stefan’s study of competition and state aid case law has shown over 600 judgments, orders and opinions which have acknowledged (some) legal effects of soft law instruments.¹⁵⁰ She draws out three overarching themes from this case law.¹⁵¹ First, she argues that soft law increasingly features in judgments of the European courts (even though, as noted above, the term ‘soft law’ is infrequently used). Second, she sets out that the EU courts recognise that such instruments can have legal effects even if they are not binding. Third, the Court

¹⁴⁶ Case C-399/12, *Germany v Council*, Opinion of AG Cruz Villalon delivered on 29 April 14 (not yet published), para 97

¹⁴⁷ *ibid* para 98

¹⁴⁸ Joined Cases C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P *Dansk Rorindustri v Commission* [2005] I-05425, para 12

¹⁴⁹ Case C-396/11 *Ministerul Public – Parchetul de pe lângă Curtea de Apel Constanța v Ciprian Vasile Radu*, Opinion of AG Sharpston delivered on 18 October 2012 (not yet published), para 48

¹⁵⁰ Oana Stefan, *Soft Law in Court: Competition Law, State Aid and the Court of Justice of the European Union* (Kluwer 2012) 57

¹⁵¹ Oana Stefan, ‘European Competition Soft Law in European Courts: A Matter of Hard Principles?’ (2008) 14(6) *European Law Journal* 753

“recognises legal effects to non-binding documents such as the notices and guidelines of the Commission, only when this serves the enforcement of certain superior principles of law, common to the European legal order and the national legal orders.”¹⁵²

This observation is partly confirmed and partly challenged by the jurisprudence on REACH, discussed below. In her more recent work, Stefan suggests that the European Courts have “kept pace only to a limited extent with the changes at the regulatory level” and that they are ready to acknowledge limited legal effects of soft law in some areas, but not in others.¹⁵³ The following section considers what the EU courts have said about post legislative notices, guidelines and guidance, which is of particular relevance for this thesis. The section after that offers an account of case law on REACH and ECHA’s guidance. What the work in this thesis means for EU jurisprudence in this area is set out in Chapter 10.

EU Jurisprudence on Notices, Guidelines and Guidance

Two interesting matters arise: the first is whether post legislative soft norms (notices, guidelines, guidance documents etc) have legal effects (and under what conditions) for the purposes of Article 263 TFEU; and the second is how those guidance documents are used by the EU courts to shape their own decisions.¹⁵⁴ As to the first question, following a detailed review of associated case law, Scott argues that there are three situations in which post legislative guidance may have legal effects (and thus be amenable to review by the EU courts).¹⁵⁵ The first is where guidance is construed as introducing new obligations and adding to the relevant EU legislation (this maps well with the instances of ‘translation’ and ‘extrapolation’ by ECHA of the provisions in REACH highlighted in this thesis); the second situation is where guidance sets out how an EU institution will exercise its discretionary and supervisory powers; and the third is where certain measures, through express statement in legislation or via

¹⁵² *ibid* 772

¹⁵³ Oana Stefan, ‘Helping Loose Ends Meet? The Judicial Acknowledgement of Soft Law as a Tool of Multi-Level Governance’ (2014) 21(2) *Maastricht Journal of European and Comparative Law* 359, 379

¹⁵⁴ Emilia Korkea-aho, ‘Laws in Progress: Reconceptualizing Accountability Strategies in the Era of Framework Norms’ (2013) 2(2) *Transnational Environmental Law* 363, 379

¹⁵⁵ Scott (n 127) 340-342

implication, may be binding on Member States. While many guidance documents are at pains to clearly state that they are simply guidance and are not legally binding, “non-binding should not be equated with an absence of (legal) effects and careful, contextual analysis is required to assess and evaluate their nature and extent.”¹⁵⁶ As noted above, ECHA’s core guidance documents clearly state that they do not constitute “legal advice.” However, these guidance documents do not say (and would be inaccurate were they to say) that they do not create legal effects. The challenge, however, for the majority of ECHA’s guidance being amenable to judicial review is in whether the EU courts would consider that the advice given was simply “fleshing out” or making more explicit existing legislative obligations (which has previously been said not to be reviewable),¹⁵⁷ or whether that guidance added to the underlying hard law (which would open the guidance up to review). This thesis shows how the “fleshing out” of REACH by ECHA’s guidance (the amplification and standardisation functions) is several orders of magnitude greater than the underlying Regulation. If the EU courts refused to consider this guidance, they would (wrongly) be excluding the majority of norms that shape the operationalization of the EU’s flagship chemicals regime. This thesis therefore suggests that the EU courts need to revisit this question of “fleshing out”.

As to the second question, on the use of post legislative soft norms by the EU courts, there are, as has been observed by other academics, only a small number of cases on which to draw.¹⁵⁸ Despite this, Scott suggests there is a strong argument for enabling judicial review of post-legislative guidance documents, because “guidance of this kind is intended to interpret a binding legal obligation and to shape the manner in which this binding legal obligation is interpreted, enforced and applied.”¹⁵⁹ I would agree. In *Expedia*, a preliminary reference from the French Cour de Cassation, the ECJ was asked to consider whether a Commission notice in the area of competition law was binding. The decision of the Court is quite clear, and quite brief: the notice is not binding on Member States, but imposes a limit on the exercise of the

¹⁵⁶ *ibid* 331

¹⁵⁷ Case C-325/91 *France v Commission* [1993] ECR I-3283, para 14

¹⁵⁸ Scott (n 127); Korkea-aho (n 154) 379

¹⁵⁹ Scott (n 127) 350

Commission's discretion.¹⁶⁰ This follows on from a number of earlier cases which were clear that administrative guidelines created by the Commission, while not "rules of law...form rules of practice from which the administration may not depart in an individual case without giving reasons."¹⁶¹

However, the Opinion of Advocate General Kokott in *Expedia* is worth exploring in some depth (not least because her observations arguably could influence whether and how ECHA's guidance is justiciable).¹⁶² AG Kokott argued that the Commission notice did not have binding legal effect because of, "the wording of the notice, ...its purpose and the context in which it was adopted."¹⁶³ As for the wording of the notice, the fact that it clearly stated that it was only the Commission's view, and was 'without prejudice' to any interpretation of Article 81 EC, meant that it could not be binding.¹⁶⁴ The same could be said for each of ECHA's core guidance documents, which come with the clear statement that they do not constitute legal advice. However, to allow public bodies to avoid judicial scrutiny through the blanket use of boilerplate provisions is too broad brush an approach and clearly wrong.

As for purpose, AG Kokott commented that the Commission's purpose in issuing the notices, "was to make transparent its administrative practice...and to provide guidance with useful information on interpretation."¹⁶⁵ These purposes, she argued, suggested that the notices were not binding (although the logic of this argument is hard to follow and is not well made out in the Opinion). Indeed, and in line with *Scott*, the opposite is true - the fact that these norms help to interpret underlying hard norms make them wholly fitting candidates for judicial review. Finally, the context of the Commission's notice also meant that it was not intended to be binding. Here, AG Kokott suggested that one relevant consideration was that: "The Commission issued the notice, not by virtue of its legislative powers, but in its capacity as the competition

¹⁶⁰ Case C-226/11 *Expedia Inc v Competition Authority*, delivered on 13 December 2012 (not yet published) paras 28 and 29

¹⁶¹ *Dansk Rorindustri* (n 37) para 35. See also: Case T-187-99 *Agrana Zucker v Commission* [2001] ECR II-1587, para 56; Case T-214/95 *Vlaamse Gewest v Commission* [1998] ECR II-717, paras 79 and 89; Case C-520/09 P *Arkema v Commission* [2011] ECR I-08901, para 88

¹⁶² Case C-226/11 *Expedia Inc v Competition Authority*, Opinion of AG Kokott delivered on 6 September 2012 (not yet published)

¹⁶³ *ibid* para 26

¹⁶⁴ Opinion of AG Kokott (n 162) para 27

¹⁶⁵ Opinion of AG Kokott (n 162) para 28

authority of the European Union.”¹⁶⁶ However, when ECHA issues guidance, it does so both as the EU’s central authority for chemicals regulation and because of its legislative mandate to create guidance. Despite the wording, purpose and context of the Commission’s notice suggesting that it was not legally binding, AG Kokott did suggest: (i) that, as an instrument of soft law, the notice could bind the Commission;¹⁶⁷ (ii) the notices, as soft law, contributed to the “fundamental aim” of the uniform and effective application of EU law;¹⁶⁸ and (iii) national authorities and courts “must take due account” of the Commission’s notices.¹⁶⁹ It is interesting that AG Kokott developed this line of reasoning as she had already noted in her Opinion that the ECJ had previously decided that Commission notices in the area of EU competition law do *not* have binding legal effect.¹⁷⁰ Certainly, as noted above, the ECJ, in its ruling in *Expedia*, did not go into any depth, at all, on how/why soft law, such as Commission notices, are or could be justiciable.

AG Kokott’s observations, as to the fundamental importance of soft norms, have been seen in other cases. In a matter concerning compliance by the UK with an EU Directive on urban waste water treatment, Advocate General Mengozzi commented that it would have been, “highly desirable for at least the Commission, if not the legislature, to provide clarification [on the Directive] by drawing up and publishing appropriate guidance on interpretation.”¹⁷¹ In the ECJ ruling on this case, the Court commented that, “[S]ince the concept of ‘unusually heavy rainfall’ is not defined by Directive 91/271, it is legitimate for the Commission, in carrying out its supervision of compliance with European Union law, to adopt guidelines.”¹⁷² What is interesting about the language used by the ECJ is that it could be argued that it is inappropriate for guidance to be issued where matters are set out, in sufficient depth, in the underlying legislation. This is not the case with REACH – the guidance, in instances, provides further corpulence to matters already quite well fleshed out in the Regulation (for example, as regards the content of an applicant’s registration dossier).

¹⁶⁶ Opinion of AG Kokott (n 162) para 29

¹⁶⁷ Opinion of AG Kokott (n 162) para 36

¹⁶⁸ Opinion of AG Kokott (n 162) para 37

¹⁶⁹ Opinion of AG Kokott (n 162) para 38

¹⁷⁰ Opinion of AG Kokott (n 162) para 26; Case C-360/09 *Pfleiderer AG v Bundeskartellamt* [2011] ECR I-0000, para 21

¹⁷¹ Case C-301/10 *Commission v UK*, Opinion of AG Mengozzi, delivered on 26 January 2012, para 29 (not yet published)

¹⁷² Case C-301/10 *Commission v UK*, ECJ judgment of 18 October 2012, para 61 (not yet published)

In *Lodato*, an interesting case concerning alternative methods for calculating the ‘growth in employment’ in two different sets of Commission guidelines, Advocate General Ruiz-Jarabo Colomer commented on how post legislative norms are able to shape the underlying hard law: “Articles 87 EC and 88 EC represent the hard law applicable in that area, and the guidelines the soft law for its interpretation.”¹⁷³ He argued that, in the 1989 case *Grimaldi*,¹⁷⁴ the ECJ confirmed its jurisdiction in preliminary rulings to interpret soft law provisions adopted on the basis of the Treaty, stating that such measures are not lacking in legal effects.¹⁷⁵ This is, with respect, somewhat of a leap: first, the Court in *Grimaldi* never used the term ‘soft law’; and second, in *Grimaldi*, the Court was concerned with a Commission Recommendation which contained no reference to any other relevant legislation (which is arguably different to Commission guidelines that link to, and build on, EU legislation). On the latter point, the Advocate General acknowledges (in a footnote) this as a potential issue, notes academic concerns over using *Grimaldi* for other soft norms, but ultimately concludes that, “there is no serious impediment to extending this case-law to other forms of soft law such as guidelines.”¹⁷⁶ Using *Grimaldi*, AG Ruiz-Jarabo Colomer argues that national courts must “take into consideration” soft law provisions when deciding cases before them, in particular where such provisions clarify the national rules enacted in order to implement them, or where they “supplement legally binding Community rules.”¹⁷⁷ The use of ‘supplement’ here is interesting as regards ECHA’s guidance (and particularly its translation and extrapolation functions) and what this means for how the EU courts should think afresh about soft law. This is discussed further in Chapter 10. In *BP Chemicals Ltd v Commission*, the then CFI ruled that a soft law Commission framework was, “one of the factors on which the Community judicature may rely in determining the scope to be attributed to a term used in a Community legislative measure.”¹⁷⁸

¹⁷³ Case C-415/07 *Lodato Gennaro & C. SpA v INPS and SCCI* [2009] ECR I-02599, Opinion of AG Ruiz-Jarabo Colomer, para 3

¹⁷⁴ Case C-322/88 *Salvatore Grimaldi v Fonds des maladies professionnelles* [1989] ECR 4407, paras 8 and 18.

¹⁷⁵ *ibid*

¹⁷⁶ Opinion of AG Ruiz-Jarabo Colomer (n 173) footnote 11

¹⁷⁷ Opinion of AG Ruiz-Jarabo Colomer (n 173) para 34

¹⁷⁸ Case T-184/97 *BP Chemicals Ltd v Commission* 2000 II-03145, para 64

The use by AG Ruiz-Jarabo Colomer of previous case law on non-yoked soft law in a hybrid context had also been seen in the earlier case of *Italy v Commission*, concerning state aid.¹⁷⁹ Here, the ECJ noted that while guidelines setting out the approach that the Commission intended to take “certainly help to ensure that it acts in a manner which is transparent, foreseeable and consistent with legal certainty, they cannot bind the Court.”¹⁸⁰ Despite this lack of bindingness, “they may form a useful point of reference.”¹⁸¹ The Court based its decision on earlier case law which had held the same points but, (as with *Lodato*) in the previous cases the guidance was not yoked to hard law, but operated in place of it.¹⁸² It may simply be that the EU courts consider the distinctions between different types of soft norm to be irrelevant.

The preceding review of EU jurisprudence has shown some acknowledgements that post legislative soft norms can bind the issuer, that these norms can both help in the interpretation of, and as a supplement to, legally binding EU rules; and that they can assist with the uniform and effective application of EU law. However, it is also fair to say that the cases on post legislative norms (compared to other, non-yoked forms of soft law) are few in number, and that most of the substantial commentaries are seen in the opinions of the Advocates General and not in the rulings of the EU courts. The following section looks specifically at case law on REACH, and at commentary on ECHA guidance.

What The Courts Have Said About REACH, ECHA and Post Legislative Guidance

As of 31 July 2014, there have been 23 cases on REACH in the EU courts;¹⁸³ 15 before the General Court; and eight before the Court of Justice.¹⁸⁴ In only four of

¹⁷⁹ Case C-310/99 *Italy v Commission* [2002] I-02289

¹⁸⁰ *ibid* para 52

¹⁸¹ *ibid*

¹⁸² Case C-387/97 *Commission v Greece* [2000] ECR I-5047, in particular paras 87 and 89

¹⁸³ Via a Curia case law search, “on REACH” here means that the Regulation was referred to at some point in each of the cases, whether or not REACH was the main issue at play. Interestingly, ECHA houses a section on its website headed “Case Law”, but only references 14 cases. See: <http://echa.europa.eu/regulations/reach/legislation>

¹⁸⁴ Case C-558/07 *S.P.C.M. SA and Others v SoS for Environment, Food and Rural Affairs* [2009] ECR I-05783 Case C-358/11 *Lapin v Lapin* (not yet published); Cases C-625/11P and C-626/11P *PPG and SNF v ECHA* (not yet published); Case T-1/10 *RENV -PPG and SNF v ECHA* (not yet published); Case T-93/10 *Bilbaina de Alquitranes, SA and Others v ECHA* (not yet published); Case T-94/10 *Rütgers Germany GmbH and Others v ECHA* (not yet published); Case T-95/10: *Cindu Chemicals BV and Others v ECHA*; Case T-96/10: *Rütgers Germany GmbH and Others v ECHA* (not yet published); Case

these cases is there any reference *at all* to ECHA's guidance: (i) in *SPCM SA v SoS for the Environment Food and Rural Affairs*,¹⁸⁵ the Court referenced Article 27(3) of REACH, which itself references cost-sharing guidance to be produced by ECHA;¹⁸⁶ (ii) in *Bilbaina*, the ECJ set out that the claimant had referred to ECHA guidance on the identification and naming of substances in its pleadings;¹⁸⁷ and (iii) in *Etimine* and in *Nickel Institute* (separate cases on the same issue handed down on the same day) Advocate General Bot cites, in each case in a footnote, the same ECHA 'Practical Guidance' document as authority for his explanation of how the read across method works.¹⁸⁸ Given this thesis shows just how thickly ECHA's guidance is wrapped up with the Regulation, this lack of reference in the cases on REACH is striking. Others have noted how, in the *SPCM* case, Advocate General Kokott references ECHA guidance to bolster her arguments on the requirement to register monomers (and not polymers).¹⁸⁹ This is certainly true, and interesting, but AG Kokott's reference to the guidance is both fleeting and not couched in any wider terms about the use/importance/role/power/limits etc of post legislative norms. Certainly, she does not refer to, or use, ECHA's guidance in the later *Lapin* case on which she also opined.¹⁹⁰ Why the EU courts have been so silent on ECHA's guidance in their REACH rulings is unknown. Scott and Sturm have suggested that courts are able to "prompt - and create occasions for - normatively motivated and accountable inquiry and remediation by relevant non judicial actors in response to signals of problematic conditions or practices."¹⁹¹ Given the thinness of ECJ jurisprudence on REACH and its guidance, does this mean that the conditions and/or practices of ECHA's guidance are not then

T-268/10: *PPG and SNF v ECHA* [2011] ECR II-06595; Case T-89/13 *Calestep v ECHA* (not yet published); Case T-346/10 *Borax Europe v ECHA* [2011] ECR II-06629; Case T-368/11 *PPG and Others v Commission* (not yet published); Case T-456/11 *ICdA and Others v Commission* (not yet published); C-287/13 *P Bilbaina de Alquitrans and Others v ECHA* (not yet published); Case C-199/13 *P PPG v ECHA* (not yet published); Case C-265/10 *Commission v Belgium* [2011] ECR I-00068; Case C-15/10 *Etimine* [2011] ECR I-06681; Case C-14/10 *Nickel Institute v SoS for Work and Pensions* [2011] ECR I-06609; Case T-466/13 *Herman Tollius v ECHA* (not yet published); Case T-343/10 *Etimine v ECHA*; Case T-539/08 *Etimine v Commission* [2011] ECR II-06611; Case T-532/08 *Norlisk Nicekl Harjavalta v Commission* [2010] ECR II-03959

¹⁸⁵ *S.P.C.M* (n 184) para 13

¹⁸⁶ AG Kokott also referred to ECHA's guidance in her Opinion on this case. This is discussed in more depth below.

¹⁸⁷ *Bilbaina de Alquitrans* (n 184) Order of the Court 22 May 2014 (not yet published) para 28. But nothing else is said in the case on that guidance.

¹⁸⁸ *Etimine v SoS for Work and Pensions* (n 73), Opinion of Advocate General Bot, para 119; *Nickel Institute* (n 184) Opinion of AG Bot, para 61

¹⁸⁹ *S.P.C.M* (n 184) Opinion of AG Kokott, para 127; *Korkea-aho* (n 43) 380

¹⁹⁰ *Lapin* (n 184) Opinion of AG Kokott, delivered on 13 December 2012 (not yet published)

¹⁹¹ Scott and Sturm (n 124) 7

problematic? Or is it that the ‘wrong’ sorts of cases (i.e. those not really about ECHA’s guidance) have so far come to court? The answer may, of course, be a blend of the two. Certainly, what is known is that, of the cases on REACH before the EU courts thus far, they have mainly been about the inclusion of substances on the Candidate List, or on Restrictions (both areas of the Regulation underpinned by detailed ECHA guidance).

In this context, what are more interesting than the decisions of the EU courts on REACH are the rulings of ECHA’s own Board of Appeal. To date, 25 appeals have been made to the Board, of which 9 were withdrawn.¹⁹² Of the remaining 16, four contain noteworthy observations about the nature of ECHA’s guidance. It may be that the Board of Appeal says more about ECHA’s guidance because the Board members are REACH experts (and so know more about the role/function/breadth of that guidance); and/or the relative thickness of the jurisprudence may simply be a product of the cases before them. In *N.V. Elektriciteits v ECHA*, the appellant sought reimbursement of its registration fee, following the rejection by ECHA of its registration dossier.¹⁹³ Part of the case concerned the relevance and legal nature of ECHA’s frequently answered questions (‘FAQs’). Referencing the ECJ’s ruling in *Holland Malt BV v Commission*,¹⁹⁴ ECHA’s Board of Appeal commented that, “...it is clear that while administrative guidance does not constitute a source of law, which would be comparable to legislation, such administrative guidance, if published, can nevertheless bind the administrative body in question.”¹⁹⁵ In *N.V. Elektriciteits*, the Board found that ECHA’s FAQs created “legitimate expectations” for registrants and ordered the repayment of the registration fee to the applicant.¹⁹⁶ In many ways, this decision simply mirrors the existing jurisprudence of the ECJ, set out above. It is not surprising that the Board would rely on legitimate expectation as a standard of review: this is seen in other ECJ case law on soft instruments,¹⁹⁷ and is a part of a general EU principle of legal certainty. However, the Board in *N.V. Elektriciteits* also commented

¹⁹² See: <<http://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions>> accessed 10 August 2014

¹⁹³ Case A-001-2010 *N.V. Elektriciteits – Produktiemaatschappij Zuid-Nederland EPZ v ECHA*, 10 October 2011 - see: <http://echa.europa.eu/documents/10162/13575/a_001_2010_decision_en.pdf> accessed 10 August 2014

¹⁹⁴ Case C-464/09 P *Holland Malt v Commission* [2010] I-12443, para 46

¹⁹⁵ *ibid*, para 59

¹⁹⁶ *N.V. Elektriciteits* (n 193) paras 40, 88-94 and 168

¹⁹⁷ For example: *Dansk Rorindustri* (n 148) para 211

on the differences between the core guidance documents produced by ECHA and the Agency's FAQs. These comments are worth setting out in full:

“The legal nature of the FAQs needs to be distinguished from the REACH Guidance, which are drafted and issued in close co-operation with the stakeholders. Compared to the REACH Guidance, the legal nature of the FAQs is different and less complex as the Agency alone decides on the contents of the FAQs and their purpose is to directly inform registrants of the Agency's administrative practice.”¹⁹⁸

Exactly how the legal nature of FAQs is “different” to other forms of ECHA guidance is not elaborated on by the Board. Differentiation within ‘guidance’ requires us to take a hard look at what counts (and does not count) for a variety of purposes in shaping the operationalization of legislation (as discussed earlier in this Chapter and more in depth in Chapter 9). Here, the Board accepted that FAQs created “legitimate expectations” for applicants, which is important given just how many ECHA FAQs there are. Would the same be said of the other types of guidance document that ECHA produces? Is there a point at which ‘guidance’ (however so labelled) stops creating legitimate expectations or is everything that a public body puts out which impacts on the operation of underlying legislation capable of creating expectations that are legitimate? There is no clear answer to this in the existing case law.

The emphasis in *N.V. Elektriciteits* was on guidance produced by ECHA setting out the course of conduct the Agency would follow. The same theme was seen in the recent Board of Appeal decision in *Infineum UK Ltd v ECHA*,¹⁹⁹ in which the appellant argued that the Agency was requiring a greater level of detail in its registration dossier than the relevant guidance document suggested. However, unlike in *N.V. Elektriciteits*, where the Agency's guidance acted as a check on what ECHA could and could not do, the Board of Appeal in *Infineum* found that the Agency was permitted to go beyond what was set out in its guidance, because of the underlying human health and environmental protection objectives found in REACH, and because

¹⁹⁸ *N.V. Elektriciteits* (n 193) para 56

¹⁹⁹ Case A-001-2013 *Infineum UK Ltd v ECHA*, 9 April 2014 – see: http://echa.europa.eu/documents/10162/13575/a-001-2013_boa_decision_en.pdf accessed 10 August 2014

of ECHA's need to identify substances of unknown or variable composition or biological origin.²⁰⁰ This case thus suggests that while the guidance produced by ECHA will normally act as a check on the Agency's discretion, this limitation can be avoided when inconsistent with the fundamental tenets of the underlying legislation. This case confirms Stefan's third conclusion from her review of EU competition law jurisprudence (discussed above). This also reinforces Scott's argument, discussed above, as to the need for the EU courts to take a hard look at post legislative soft norms because they are inextricably linked to, and should be judged by, the underlying hard law.

In *Lanxess Deutschland GmbH v ECHA*, the Agency asked the applicant to provide a developmental toxicity study on a second animal species, in addition to a study on a first animal species in the applicant's registration dossier.²⁰¹ Here, ECHA argued that the requirement for the second study was clear in its guidance.²⁰² The Board of Appeal disagreed, and argued that, "rather than clarifying the interpretation of those provisions, the Guidance may, although not claimed by the Appellant in these proceedings, contribute to a misunderstanding thereof."²⁰³ This is striking: ECHA puts out guidance that elaborates on REACH and which shapes the operation of the legislation by channelling registrants, Member States and the Agency itself down certain paths of conduct. The Board of Appeal is suggesting that some of that channelling may be inaccurate. Certainly, this thesis has shown a number of other instances where ECHA's guidance is not clear and may cause confusion. However, it is worth noting that in this particular case the Board found that the request by ECHA for a second developmental toxicity study was legitimate, and flowed directly from the text of REACH itself.²⁰⁴ Here, and in *Infineum*, the backstopped hard law of REACH perfects imperfections in ECHA's guidance to the advantage of the Agency.

²⁰⁰ *ibid* paras 59, 65ff and 95

²⁰¹ Case A-004-2012 *Lanxess Deutschland GmbH v ECHA*, 10 October 2013 – see: http://echa.europa.eu/documents/10162/13575/a-004-2012_boa_decision_en.pdf accessed 10 August 2014

²⁰² ECHA, 'Guidance on Information Requirements and Chemical Safety Assessment' (Version 1.0 of May 2008)

²⁰³ *Lanxess* (n 201) para 108

²⁰⁴ *ibid* para 109

Finally, in *Momentive Specialty Chemicals v ECHA*, the Agency had rejected the appellants' registration dossier as inadequate. Here, Momentive had failed to comply with ECHA's guidance on read-across (where endpoint information for one chemical is used to predict the same endpoint for another chemical). In this case, the ECHA Board of Appeal commented that,

“...in not following the available guidance the Appellant did not avail itself of a tool designed to help registrants to prepare and submit their read-across proposals in an effective way. The Board of Appeal observes that in so doing the Appellant may have required additional effort to justify its case compared with following the approach described in the guidance.”²⁰⁵

This comment suggests that while ECHA's guidance is not necessarily binding on third parties, in that registrants are not obliged to follow it, where third parties use standards or take approaches *different* to those set out in the Agency's guidance, “additional effort” will be required of them to justify taking that path. This suggests that ECHA's guidance may, in practice, only really be semi-soft. This is explored in more depth in Chapter 9. Looking to the future, it will be interesting to see whether the EU courts engage with any of the jurisprudence discussed above from the Board of Appeal, either in the context of REACH or more generally. There is, it is suggested, greater nuance in the rulings from the Board on post legislative norms than in the rulings of the EU courts.

Conclusions

This Chapter has explored ECHA, the new regulator for chemicals created under REACH. Established given the “...need to ensure effective management of the technical, scientific and administrative aspects of [REACH] at Community level”,²⁰⁶ the influence of ECHA and what it does on a day-to-day basis puts it at the very heart of modern chemicals regulation. ECHA is, however, not the only EU regulatory

²⁰⁵ Case A-006-2012 *Momentive Specialty Chemicals v ECHA*, 13 February 2014, para 61 – see: <http://echa.europa.eu/documents/10162/13575/a_006_2012_boa_decision_en.pdf> accessed 10 August 2014

²⁰⁶ Recital 15

agency with oversight of chemicals. Others (such as the European Environment Agency and the European Food Standards Agency) also play a role. There are then, in addition, a whole host of regulators with responsibility for chemicals control in the 28 Member States. At the EU level, this creates a regulatory landscape with varying topology. The Agency has grown since its inception, from 38 staff in 2007 to over 500 in 2013, and is likely to expand further as it becomes more deeply embedded into EU chemicals regulation and takes the role as responsible regulator for laws other than REACH.

Since 2003, more than one million words of official guidance have been produced by ECHA on REACH. The Agency's Document Library (the central repository for publicly available ECHA documents) contains 482 separate 'support' documents. This is made up of: (a) 138 guidance documents; (b) 34 Helpdesk documents; (c) 185 documents relating to IT Tools; and (d) 67 Manuals.²⁰⁷ The power given to ECHA to produce such 'support' comes, in generic form, from Article 77(2) of REACH and also in a small number of specific provisions in the Regulation that directly mandate ECHA to produce guidance. The Agency accepts that some of its guidance is dense and complex and is working on making the documents more accessible and, where possible, more simple.²⁰⁸

The breadth of the guidance produced by ECHA and the variety of forms that that guidance takes is striking. What is also interesting is the explicit acknowledgment by the Agency of a hierarchy of soft law norms within the differing types of guidance that it produces. So, for example, ECHA labels everything save for the core guidance documents as "quasi guidance", with the intent that these are "in simple terms" and particularly intended for SMEs.²⁰⁹ The mechanics of how guidance is produced and updated by ECHA is also worthy of study. Many of the guidance documents were produced prior to the entry into force of REACH as 'REACH Implementation Projects'/RIPs. Little publicly available information on how those RIPs were developed remains. Not every update to ECHA's guidance is consulted on, and wide discretion is given to ECHA's Secretariat who decide whom to consult and on the

²⁰⁷ <<http://echa.europa.eu/web/guest/support/documents-library>> accessed 10 August 2014

²⁰⁸ *ibid*

²⁰⁹ *ibid*

time frames given for consultation.²¹⁰ Much of that consultation is ‘closed’ in that it involves experts “whose nominations have been received by a specified deadline”²¹¹ and who are then formed into so-called Partner Expert Groups (‘PEGs’).²¹² The ECHA website does not detail lists of experts within PEGs formed as part of previous consultations on guidance. Only in limited situations (for example, for entirely new guidance) will ECHA engage in full public consultation. As a consequence, the procedures for guidance production and amendment lack full participation and transparency. These are causes for concern.

The review of case law in this Chapter has shown how the EU courts are willing, in general, to consider and use soft norms to a certain degree, but that the volume of case law specifically on post legislative guidance is limited. The cases to date on REACH in the EU courts have said almost nothing on ECHA’s guidance. This, in and of itself, is interesting. More has been said by ECHA’s own Board of Appeal, but even that jurisprudence is somewhat thin. What this thesis means for EU law, and EU jurisprudence, is taken up in Chapter 10. However, it is worth noting here that the potential for the EU courts to act as an effective check on the exercise of power by ECHA in creating and promulgating guidance seems small. The following Chapters look at the various elements of REACH and explore, in detail, how ECHA’s post legislative guidance shapes the operation of the Regulation. As will be recalled from Chapter 1, four forms of shaping are suggested: amplification; standardisation; translation; and extrapolation. It is submitted that amplification occurs where guidance produced by ECHA goes beyond, but is not in direct contradiction with, the text of the Regulation. Standardisation is argued to be 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

²¹⁰ *ibid*

²¹¹ It is not clear what this deadline is or how it is disseminated.

²¹² ECHA (n 103) 5

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. The Chapter which follows looks at information creation under REACH and the role of SIEFs.

CHAPTER 5

INFORMATION CREATION AND SUBSTANCE INFORMATION EXCHANGE FORA

Let us return to the example of the (hypothetical) chemical *legalene* (first introduced in Chapter 3). This Chapter sets out how information on this substance comes to be generated. While REACH obliges manufacturers and importers to register their substances, the Regulation is almost silent as to the underlying mechanics of data generation and assessment. All that is said is that those who have pre-registered are obliged to come together to share certain data and to generate missing information (in groupings called Substance Information Exchange Fora, or SIEFs). Exactly how such sharing and generation should happen is not specified, nor does REACH detail the form of SIEF or how it should be run. The Regulation is thus underpinned by the self regulation of pre-registrants (who number over 100,000),¹ shepherded via a series of guidance documents produced by ECHA (discussed below). For our ten *legalene* manufacturers, coming together, sharing data, agreeing on new tests and executing such tests might not be a particularly difficult matter. However, what about the Pre-Registrants of *jurisite*, a (hypothetical) substance used in the powdering of judges' wigs, who number 3,000? For them, translating the bare command in REACH to share data may be much more problematic. It is estimated that more than 3,500 SIEFS have 100 members (and more than 400 have more than 500 members.)² The simplicity of agreement on data sharing obviously diminishes as a function of the size of the SIEF.

This Chapter outlines the processes of SIEF formation and operation, moving from the need to agree on substance "sameness" to questions of SIEF structure and ordering to the core task of data sharing (and the corollary need to share costs). In particular, the Chapter comments on the practical difficulties experienced in 'real life' SIEFs. To date, there have been a variety of issues with SIEFs, including: the

¹ ECHA, 'Companies Submitted Over 2 Million Pre-Registrations by Deadline' (Press Release, ECHA PR/08/54, 2 December 2008) – see: http://echa.europa.eu/documents/10162/13585/pr_08_54_end_of_preregistration_20081202_en.pdf accessed 10 August 2014

² Hugo Waeterschoot, 'How to manage a SIEF with thousands of members' (Presentation at REACH Lead Registrants Workshop, 11 September 2009) 3

administrative and legal burdens on companies in their creation and operation; issues with communication in so-called “monster SIEFs” (that have thousands of members); divergence of opinion over SIEF membership (the question of substance “sameness”); and problems in data exchange.³

There are three key ECHA guidance documents relevant to SIEFs and data generation and assessment: (a) Guidance on Data Sharing;⁴ (b) Guidance on Information Requirements and Chemical Safety Assessment (discussed more fully in the following Chapter); and (c) Guidance for Identification and Naming of Substances.⁵ In addition, ECHA has produced two ‘User Manuals’ which assist registrants with the IT aspects of SIEF formation and data sharing.⁶ Of all the elements of REACH, the creation and running of SIEFs is *the* area in which guidance produced by ECHA amplifies the text of the Regulation and shapes the day to day operation of the legislation. It is submitted that without this guidance, data generation, assessment and sharing under REACH would fail.

REACH and SIEFs

Article 29 is notable for its lack of specificity. It states that,

“All potential registrants, downstream users and third parties who have submitted information to the Agency... for the same phase-in substance...shall be participants in a substance information exchange forum (SIEF).”⁷

The aim of each SIEF is to facilitate information exchange (avoiding duplicity of chemical tests),⁸ with SIEF participants providing each other with certain existing testing data, identifying the need for additional testing and arranging for such testing to be undertaken.⁹ Aside from Article 30 (discussed in depth below), which amounts

³ Geert Dancet, ‘Conclusions’ (Presentation at REACH Lead Registrants Workshop, 11 September 2009) 5

⁴ ECHA, ‘Guidance on Data Sharing’ (Version 2.0, April 2012) – see: <http://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf> accessed 10 August 2014 (hereafter, ‘Guidance on Data Sharing’)

⁵ ECHA, ‘Guidance on the Naming and Identification of Substances’, (Version 1.2, March 2012) – see: <http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf> accessed 10 August 2014

⁶ <http://echa.europa.eu/sief_en.asp> accessed 10 August 2014

⁷ Article 29(1)

⁸ Article 29(2)

⁹ Article 29(3)

to a limited outline of how data should be shared in a SIEF, REACH is totally silent on the creation, formation, organisation and operation of these entities. As the Health and Safety Executive in the UK puts it, “REACH does not set precise rules for how a SIEF should operate. Consequently, this is up to the individual SIEF members collectively.”¹⁰

The Pre-SIEF

Reading the text of the Regulation, it appears as though SIEFs were expected to spontaneously appear. The reality has been much more complicated, as perhaps should have been foreseen for mandatory groupings of thousands of companies within and without the EU. Given this, the practice of having a pre-SIEF has emerged. ECHA comments that “The concept of pre-SIEFs was not foreseen in the REACH Regulation, but was introduced, with support from industry, to bring pre-registrants together and facilitate SIEF formation”.¹¹ Prior to the formation of the SIEF, various matters need to be agreed, the most fundamental amounting to a decision on the limits of the membership of the SIEF (i.e. the basic question of who should, and who should not, be a part of the SIEF).

As part of Pre-Registration, REACH-IT creates a dedicated web page for Pre-Registrants of the “same” substance. This allows Pre-Registrants to see who else has Pre-Registered their substance. To take our *legalene* example, all ten manufacturers and importers would pre-register. Then, via REACH-IT, they would be able to see who had also pre-registered *legalene* and to then begin discussions on the formation of the SIEF. To facilitate this process, REACH-IT, ECHA’s web based software for chemicals data management, allows for a pre-registrant to volunteer as a SIEF Formation Facilitator. This role does not exist within REACH, which has raised a number of issues, mainly centred on the fact that, “Any pre-registrant may volunteer via REACH IT to be the SFF” (own emphasis added).¹² The title of SFF is claimed; it is not bestowed following agreement among pre-registrants. The SFF does not have to be, for example, the pre-registrant with the largest production volume of the particular

¹⁰ UK REACH Competent Authority, ‘Information Leaflet Number 17 – REACH – Substance Information Exchange Forum’ (March 2009)

¹¹ <http://echa.europa.eu/sief_en.asp> accessed 10 August 2014

¹² ECHA, ‘SIEF – Key Principles’ (13 February 2009) 2

substance (who may have an interest in being SFF as their registration deadline will be sooner than those of the other pre-registrants) or the largest pre-registrant entity (who might have better resources or expertise to bring to the role of SFF). Given this, there have been issues of “cowboy SFFs”.¹³ Here, ECHA advises that,

“Where the current SFF isn’t working, or is perhaps using the pre-SIEF as an opportunity to earn money or blocking or slowing down the process... SIEF members are free to work around the SFF, perhaps using their own information text field in the pre-SIEF page in REACH IT to post comments, or outside of REACH IT, perhaps via their own website or webpage”.¹⁴

The tone of this advice is somewhat odd. On the one hand, a pre-SIEF is obligatory (despite not being in the Regulation) through the way in which the REACH-IT system works. On the other, ECHA seems keen to distance itself from the mechanics of (and issues arising from) SIEF formation. There is a real lack of guidance on the pre-SIEF in ECHA’s Guidance on Data Sharing and the Agency simply points out that, “SIEF formation is industry’s responsibility.”¹⁵ It is also notable that the steering (set out above) from ECHA on pre-SIEF formation is set out in ‘Top Tips’ and ‘Key Principles’ documents and not in the core guidance. In practice, agreement on the SIEF has, in instances, taken months of negotiation and renegotiation.¹⁶

The Formation of the SIEF

REACH is silent as to exactly when and how a SIEF is formed. ECHA, however, in its Guidance on Data Sharing, states that,

“...a SIEF is formed when the Potential Registrants of a substance in the pre-registration list, actually agree that they effectively manufacture, intend to manufacture or import a substance that is sufficiently similar to allow a valid joint submission of data”.¹⁷

This is an example of the Agency extrapolating from a gap in text of REACH. The language used here is interesting as it diverges from the language in the Regulation.

¹³ Karl-Franz Torges, ‘A consultant’s view of the lessons learned’ (2011) Chemical Watch 8, 8

¹⁴ ECHA, ‘Getting Started in SIEFs – Top Tips’ (24 April 2009) 2

¹⁵ Guidance on Data Sharing, 31

¹⁶ Uwe Wolfmeier, ‘What to bear in mind when becoming Lead Registrant’ (Presentation at REACH Lead Registrants Workshop, 11 September 2009) 3

¹⁷ Guidance on Data Sharing, 37

REACH talks of SIEFs being comprised of those who have pre-registered the “same” substance; ECHA (perhaps accepting that questions of sameness can be overly difficult; discussed below) talks of substances that are “sufficiently similar”. The Guidance also sees SIEF formation resting on ‘actual agreement’ and not, as is envisaged by REACH, simply operating via the fiat of pre-registration. In this regard, it is submitted that the function of this Guidance is to translate the text of REACH into something which works in practice for the day to day operation of the Regulation. Further instances of translation are seen later on in this Chapter.

As a starting point, a wide discretion is granted to manufacturers and importers as to the formation of a SIEF: the SIEF comes into existence when the manufacturers and importers agree that they are each intending to register the “same”/“sufficiently similar” substance. ECHA will not become involved in refereeing questions of formation and advises companies to contact trade associations if necessary.¹⁸ The power of trade associations as to this aspect of REACH (and elsewhere) is significant. ECHA details 62 separate, industry-based stakeholder organisations with which it works, from the large and generic (including Cefic, the European Chemical Industry Council) to the small and specific (including AECM, the Association of European Candle Manufacturers).¹⁹ Many of these trade associations provide their own guidance on REACH. Cefic, for example, has 83 individual REACH guidance documents or tools, of which 19 touch on the formation and operation of SIEFs.²⁰ These trade associations, and the guidance they provide, add another layer of post legislative norm elaboration for REACH. Whether or not such ‘counts’ as soft law is explored in Chapter 9.

Because of the lack of specificity in REACH on SIEF formation, it is perfectly possible for a manufacturer or importer who should properly be a member of a SIEF to be excluded from that SIEF (and potentially to be forced to register alone). It would also be possible, in theory, for SIEFs to be used to exclude parties for competitive advantage. Despite this, the Agency is quite clear when it states that it will not,

¹⁸ ECHA (n 12) 2

¹⁹ <<http://echa.europa.eu/web/guest/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations>> accessed 10 August 2014

²⁰ <<http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/>> accessed 10 August 2014

“confirm or question the creation of a particular SIEF.”²¹ The lack of willingness on the part of ECHA to police the formation of SIEFs may mean that certain pre-registrants (for example, SMEs) may be excluded where other pre-registrants consider that they should not belong to the same SIEF. The treatment of SMEs in SIEFs was raised as a particular concern in ECHA’s 2011 report on the operation of REACH and by the Commission in their review of the Regulation in 2012.²² ECHA has no power to order (and REACH does not provide for) the mandatory inclusion in a SIEF of a particular Pre-Registrant.

Difficulties with Sameness

Given the above, it is thus perfectly possible for two manufacturers of a substance which could be considered the “same” to participate in two different SIEFs. The obvious follow on consequence of this is that those two manufacturers may well submit different testing data as part of the Registration process. What is clear then is that the question of whether one substance is the “same” as another is key. For the majority of lawyers (and others without specialist chemical expertise), the identification of a substance would seem like a simple matter. Substance A is carbon; Substance B is mercury; Substance C is nickel. For those with more than a high school appreciation of the sciences, chemical identification can be horrendously complex. This is partly due to the way in which chemicals have been inventoried in the EU and partly due to complexities in the substances themselves. Under the pre-REACH chemicals regime in the EU, there were three separate inventories of chemicals:²³ EINECS²⁴, ELINCS,²⁵ and NLP.²⁶ EINECS lists chemicals on the EU market between 1 January 1971 and 18 September 1981; ELINCS lists chemicals which were notified to the Commission and placed on the market after 18 September

²¹ ECHA, ‘Guidance on Pre-Registration and Data Sharing’ (Version 2.0, April 2012), 37 (hereafter, ‘Guidance on Pre-Registration and Data Sharing’)

²² Commission, ‘Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH: Staff Working Document ‘(SWD (2013) 25 final); European Chemicals Agency, ‘The Operation of REACH and CLP’ (Helsinki, 2011)

²³ Each can be now be found via the European Chemical Substances Information System, here: <<http://esis.jrc.ec.europa.eu/>> accessed 10 August 2014

²⁴ The European Inventory of Existing Commercial Chemical Substances

²⁵ The European List of New Chemical Substances

²⁶ The No Longer Polymers inventory

1981; and NLP contains chemicals which, as a result of change in legislation,²⁷ are no longer considered as polymers, though they once had been.²⁸ Each chemical in each of the three inventories (collectively known as the EC Inventory) has an EC number by which it can be identified.²⁹ In the context of substance identification under REACH for the purpose of “sameness” discussions in pre-SIEFs, issues arise for four reasons. The first is because the EC Inventory contains typographical errors, mistakes which are expected to be corrected during registration via REACH (for example, EC numbers could have been transcribed incorrectly).³⁰ The second is because certain of the substance descriptions in the EC Inventory are overly broad (and so could, properly, cover two or more substances that are not the “same”). The third is that for some substances, there may be more than one ‘correct’ EINECS entry and so manufacturers and importers could pre-register using different EINECS numbers. On a practical level, this could result in different SIEFs preparing different dossiers for registration on the same substance, unless the pre-registrants noticed the multiple EINECS entries and attempted to create one combined SIEF. The fourth reason for difficulties with substance identification is that there are some substances which are simply very difficult to identify, referred to as “UVCB substances” in Guidance produced by ECHA (a term, it is noted, not to be found anywhere in REACH itself, and another example of the extrapolation function of ECHA’s guidance).³¹ Under the Regulation, a substance is identified as part of Registration using the parameters set out in Section 2 of Annex VI. These include, but are not limited to, the name of the substance, its EINECS and CAS numbers, molecular formula and composition³². For UVCB substances, however, these parameters may be insufficient to allow pre-registrants to adequately identify their substances.³³ In providing advice on UVCB

²⁷ “Polymer” was redefined in Directive 67/548/EEC by Directive 92/32/EEC

²⁸ Polymers were not listed on EINECS but, following the change in the definition of “polymer”, certain chemicals (which were once “polymers”, but which were then “no longer polymers”) needed listing, hence the creation of the NLP inventory.

²⁹ Going forward, ECHA will maintain the inventory of chemicals and assign EC numbers to all non-phase in substances (which, because they are ‘new’, do not yet have numbers).

³⁰ ECHA, ‘Guidance for identification and naming of substances under REACH’ (Version 1.2, March 2012), 15 – see: <http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf> accessed 10 August 2014 (hereafter, ‘Guidance for Identification and Naming of Substances’)

³¹ “UVCB substances” are defined as “Substances of Unknown or Variable composition, Complex reaction products or Biological materials”. See: Guidance for Identification and Naming of Substances, 14

³² Sections 2.1, 2.1.3, 2.1.4, 2.2.1 and 2.3, Annex VI

³³ A description of why these parameters may not be appropriate for certain UVCBs can be found here: ECHA, ‘Guidance for Identification and Naming of Substances under REACH and CLP’ (Version 1.3, February 2014) 18ff

substances, ECHA's 'Guidance on the Identification and Naming of Substances under REACH and CLP' (discussed in depth below) performs what I suggest can be called an 'extrapolation' function: filling in the gaps created by the legislation.

For the academic lawyer, it is not (strictly) necessary to know how to identify a particular substance or to say whether Substance A is the "same" as Substance B. What is important to know is: (a) this is a complex, expert area; and (b) decisions on substance identification and "sameness" belong solely to the Pre-Registrant: neither ECHA, nor any other regulatory body, will suggest or confirm an identification. This combination of complexity and discretion mean that the formation of the SIEF (i.e. when agreement is reached on "sameness") is not always an entirely straightforward or quick process.³⁴ To assist companies on this 'sameness' question, ECHA has produced an 111 page document titled 'Guidance on Identification and Naming of Substances under REACH and CLP'. As the Agency puts it, "To ensure that the REACH processes are working properly, correct and unambiguous substance identification is essential."³⁵ As might be expected given the nature of the topic, the Guidance is dense and technical. Much of this guidance, it is suggested, is an example of standardisation. Here, REACH would still work without the guidance, but the level of debate and divergence among pre-registrants as to whether they were each intending to register the 'same' substance would be such that it is conceivable that: (a) the deadlines for registration would have been missed; and/or (b) the number of registrations (and the subsequent burdens on ECHA) would have increased significantly. Standardisation is ECHA attempting to channel those with obligations under REACH down a set course of action which, while not spelled out specifically in REACH, is in line with the aims and objectives of the Regulation.

Having discussed the formation of the SIEF and the identification of the "same" substance, the following looks at possible structures for that SIEF. What is also relevant (at least, from a practical point of view) is the internal commitment needed by SIEF members within that SIEF: commitment of expertise (which will, on occasion, even extend to the hiring of additional employees); commitment of money

³⁴ From his time in practice, the author is aware of companies who have spent more than 7 months debating the "sameness" of a single substance.

³⁵ ECHA, 'Guidance for Identification and Naming of Substances under REACH and CLP' (Version 1.3, February 2014) 18ff

(and the “buy-in” of someone senior enough within the organisation to approve budget decisions related to REACH); and commitment of time (by a large number of SIEF member employees, including those in the IT, Legal, Finance, Sales, Marketing, Toxicology/Ecotoxicology and Management teams).³⁶

The Structure of the SIEF

It is worth stating this explicitly: a SIEF is not a legal entity and it does not have a particular form.³⁷ It is merely a grouping of pre-registrants of the “same” substance and REACH itself is silent as to form and structure. ECHA comments that, “Pre-Registrants in a SIEF are free to start organising themselves as they see fit to carry out their obligations under REACH.”³⁸ How a SIEF is organised has obvious impacts on the end result: that is, the data that is transmitted to ECHA as part of Registration. Some SIEFS (especially those with very small membership) may need no internal organising rules or structure. For others, however, internal rules are vital. In our example (hypothetical) *jurisite* SIEF, the expectation that 3,000 member companies will organise themselves without some form of overriding structure or system of internal rules is nonsensical. To that end, in its Guidance on Data Sharing, the Agency has set out various “forms of [SIEF] co-operation” which pre-registrants may choose to adopt.³⁹ These vary from the more formal (consortia, discussed below) to the less formal (collaboration via IT software, with letters of access between pre-registrants sharing data).

Though not required by REACH, consortia are common vehicles for the structure and ordering of SIEFs. Cefic comments that “A consortium can be seen as a practical means to meet the legal obligations of SIEF participants and prepare for registration.”⁴⁰ Defining a consortium is not easy. ECHA comments that they the term can be,

³⁶ On this, see the discussion on “Company Preparations” in: Cefic, ‘Working together in SIEF’ (Version 2, March 2009) 10

³⁷ Guidance on Data Sharing, 132. ECHA is very explicit on this, even though the grouping of pre-registrants in the SIEF looks very much like a joint venture.

³⁸ Guidance on Data Sharing, 16

³⁹ Guidance on Data Sharing, 132-142

⁴⁰ Cefic (n 36) 8

“...used to refer to a more organised and formal type of co-operation between parties, implying either a signed agreement or the adoption of operating rules or reference to an agreed set of general rules.”⁴¹

In essence, a consortium is a legally ordered, structured grouping of some or all SIEF members. There is no obligation on SIEF members to form a consortium and, even where there is a consortium in relation to a particular SIEF, it may not include all of the SIEF members. At the same time, there can easily be more than one consortium for one substance (particularly where that substance is manufactured or imported for use in two or more different industry sectors). There are also consortia which cover a number of different SIEFs and substances, sometimes referred to as “super consortia”. In short, these entities take a variety of forms and there is no one set structure for them nor one particular method or mode of application. ECHA gives eight examples of possible consortia options, but the potential permutations of consortia and non-consortia options in any given SIEF is vast.⁴²

One common structure is to have a consortium agreement which binds the consortium members. Here, one practical difference (which may be very important for SIEFs with many pre-registrants) involves the way in which the agreement is executed. It is common for the consortium agreement (or SIEF agreement, or however else it is titled) to be bilateral, between the Lead Registrant/SIEF Leadership Team and each SIEF member. The alternative is to have each SIEF member be a party to the same document (with exchanges of mutual covenants). Cefic has created a standard form SIEF/consortia agreement. This is free to use and available on the Cefic website,⁴³ having been developed with input from the in house and external legal teams of more than 50 EU companies.⁴⁴ Whatever form of internal rules is adopted by a SIEF (whether through a consortium or otherwise), there are a core of matters upon which ex ante agreement is useful. In its Guidance on Data Sharing, ECHA details 15 different “elements of co-operation that might be included in a consortium’s activities.”⁴⁵ These include: provisions on the sharing of data and costs (on which, see below); the protection of confidentiality; and the allocation (and perhaps mitigation)

⁴¹ Guidance on Data Sharing, 132

⁴² Guidance on Data Sharing, 133-136

⁴³ <<http://cefic.org/templates/shwPublications.asp?HID=750&S=33>> accessed 10 August 2014

⁴⁴ Cefic, ‘Cefic Model SIEF Agreement: Benefits and Practical Aspects’ (Presentation at REACH Lead Registrants Workshop, 11 September 2009) 12

⁴⁵ Guidance on Data Sharing, 136-137

of liability among members. The Guidance then goes on to detail the typical clauses that may appear in a consortium agreement.⁴⁶ These include rules on membership setting out the rights and obligations of each member and how to accommodate new members or those who leave; intellectual property rights and data protection clauses; budgetary matters (payments of invoices, taxes etc); intra-consortium dispute resolution; governing law;⁴⁷ and other ‘boilerplate’ provisions. It is suggested that this guidance by ECHA is another example of standardisation: REACH requires SIEFs and ECHA engages in some form of channelling of registrants as regards the format that that SIEF takes. The Guidance on Data Sharing is striking in that it offers fairly detailed advice on creating and running consortia, while at the same time stating that the Agency has no preference as to (nor does REACH require) any particular format.

Because REACH is silent on consortia, they lack regulatory oversight. Indeed, there have been reports of certain consortia amounting to “almost secret organisations” which, while they pretend to be open to new members, in reality they are not.⁴⁸ This impacts on the regulatory burden placed on SMEs by the EU’s chemical regime, a common theme with the operation of REACH. It is also somewhat difficult to know how many consortia exist in relation to REACH. There is no obligation on them to notify ECHA (or anyone else) of their existence. Instead, certain REACH media outlets offer to publish a list of consortia; one, ran by ChemicalWatch, lists more than 300 consortia, with the vast majority covering more than one substance.⁴⁹

SIEFs and Competition Law

One important consideration for SIEF structure goes to notions of anti-competitive behaviour. Article 25(2) states that “Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.” Recital 48 states that “This Regulation shall be without prejudice to the full application of

⁴⁶ Guidance on Data Sharing, 138-139

⁴⁷ The Cefic standard form agreement does not prefer one jurisdiction over another when it comes to deciding on the governing law of the contract. This may cause some issues in the future if different courts in different countries take different views on the same clause(s).

⁴⁸ Genevieve Hilgers, ‘Frequent Challengers Observed in SIEFs’ (Presentation to REACH Lead Registrants Workshop, 11 September 2009) 3

⁴⁹ <http://chemicalwatch.com/REACH_consortia> accessed 10 August 2014

Community competition rules”. As Cefic puts it, “A SIEF is not a forum to conduct business with competitors”.⁵⁰ Here, ECHA offers practical advice in its Guidance on Data Sharing and suggests that an “independent third party” or trustee be used to receive, hold and process any information from SIEF members which would be sensitive from a competition perspective.⁵¹ Such is not set out in REACH, but is obviously consistent with this aspect of the Regulation (another example of the standardisation function of guidance). While a trustee may be appropriate for some SIEFs, for others (perhaps those which are small and contain less sophisticated members), it could be regarded as an unnecessary additional administrative burden. Let us take an (imaginary) meeting of the *legalene* SIEF.⁵² Of the ten member companies, three send their in-house lawyer, who are each well versed in EU competition rules. Four send their in-house toxicologists, who have heard of competition rules, but do not know any detail. The remaining three companies are SMEs; they have neither in house lawyers, nor in-house toxicologists and send whoever is free on the day. Given this spread of roles among the participants, it is not beyond the realms of possibility to imagine two of the toxicologists (from separate, competing companies) talking about their work and what they do over coffee (a potential breach of EU competition rules, depending on the nature of the conversation). While this is not the place to go into depth on this particular area of law,⁵³ a law such as REACH which makes mandatory the coming together of companies who manufacture or import the same substance (and so who may be direct competitors) raises serious anti-trust questions. To give just one example, companies might share information about the tonnages in which they produce chemical X and on the price of chemical X. This, in turn, could lead, intentionally or unintentionally, to price fixing or abuse of the market.

⁵⁰ CEFIC, ‘SIEF Guidance’ (September 2011) 40

⁵¹ Guidance on Data Sharing, 141-142

⁵² This example is based on a real life situation related to the author while in practice from one of his clients (an in-house lawyer with a background in competition law for a large multinational manufacturer). They attended a SIEF meeting where it was obvious some of the participants had no idea of the breadth or depth of EU competition rules.

⁵³ Instead, see: Richard Whish, *Competition Law* (7th edn, LexisNexis UK 2012)

Roles within a SIEF

In the (hypothetical) *legalene* SIEF, the ten members have a fairly easy job of coordination to comply with their obligations under REACH. Each member sends a representative to physical meetings; each responds to emails; agreement comes naturally to them. In the (hypothetical) *jurisite* SIEF, things are much different. For these so-called “monster SIEFs”, it is unrealistic to expect all SIEF members to have equal roles or indeed to contribute equally. Let us take one simple, but illuminating example. Imagine it is 1 January 2010 (the day after the end of the pre-registration period) and the *jurisite* SFF is keen to push matters forward to turn the pre-SIEF into a SIEF: how easy, on a practical level, will it be for the SIEF Formation Facilitator (‘SFF’) to organise a teleconference call or meeting in which all 3,000 *jurisite* pre-registrants will participate? If every member will not participate, who will and how will it be decided who does and who does not get involved?

Save for the position of Lead Registrant (discussed below), roles within a SIEF are not set out in REACH. In its Guidance on Data Sharing, it is set out that,

“ECHA advises all companies to decide what role they wish to take in the SIEF. For more details, please consult the ECHA website and in particular the page ‘SIEF’...”⁵⁴

However, the SIEF page on the ECHA website contains no advice whatsoever on SIEF roles.⁵⁵ Given this, SIEFs may allocate roles and organise responsibilities among their members as they see fit (matters which would, or should, be set out in the SIEF agreement or other body of internal rules). Cefic organises SIEF members into four roles (which are widely accepted throughout the EU, if not formerly endorsed by ECHA):⁵⁶ Lead Registrant (a role set out in REACH and discussed below); Involved; Passive; and Dormant.⁵⁷ As the names suggest, “involved” members actively participate in the operation of the SIEF; and “passive” members do not become

⁵⁴ Guidance on Data Sharing, 37

⁵⁵ See: <<http://echa.europa.eu/regulations/reach/substance-registration/substance-information-exchange-fora>> accessed 10 August 2014

⁵⁶ ECHA (n 12) 2

⁵⁷ <<http://cefic.org/templates/shwPublications.asp?HID=750&S=33>> accessed 10 August 2014

actively involved (for example, they may be companies who manufacture or import in small quantities, have no data to share within the SIEF and who may be happy for others to take the lead). At first glance, it may seem impossible to have a ‘dormant’ SIEF member, as Article 29 creates an obligation to share data in certain circumstances (and this in turn implies some form of participation.) However, there have been a number of problems with ‘free riders’; those who join the SIEF and then do nothing active and do not respond to communications from the SFF or Lead Registrant. ECHA advises that if a member of a SIEF does not respond to email (on two attempts) or fax (on one attempt), “there should be no further need to contact them.”⁵⁸ With these “dormant” members, it is possible that a number of pre-registrations were made either as a precaution,⁵⁹ or for commercial reasons (i.e. to gain access to a SIEF to then on-sell services or products).⁶⁰ Indeed, it is difficult to know how many of those who pre-registered will go on to register. Following a survey to members of the SIEFs in which the trade association ‘concaawe’ participates, only 20% confirmed their intention to register the substance they had pre-registered.⁶¹ For another consortium (which participates in 130 SIEFs, with 37,000 initial, potential members), they report that only 10% of pre-registrants are likely to register.⁶²

Data Holders

Article 29 of REACH details that, in addition to potential registrants, SIEFs shall also include, “downstream users and third parties who have submitted information to the Agency in accordance with Article 28.” These are termed by ECHA to be “Data Holders”, though that term does not appear in the text of the Regulation. In its Guidance on Data Sharing, ECHA details that Data Holders include any person holding information in relation to a phase-in substance that is willing to share it. It is suggested that this is ECHA amplifying the text of REACH (i.e. where guidance

⁵⁸ ECHA (n 14) 2

⁵⁹ Pre Registration was free, quick and easy. For those companies unsure of whether or not they were subject to REACH, pre-registering “just in case” may have made perfect sense at the time.

⁶⁰ The potential for commercial exploitation of SIEFs is widely accepted. See, for example, the reference in: Lothar Kistenbruegger, ‘SIEF Facilitation for Petroleum Substances’ (Presentation at REACH Lead Registrants Workshop, 11 September 2009) 6

⁶¹ *ibid*, 8

⁶² Chris Money, ‘Making Best Use of Consortia within SIEFs’ (Presentation to REACH Lead Registrants Workshop, 11 September 2009) 6

produced by ECHA goes beyond, but is not in direct contradiction with, the text of the Regulation). Data Holders might be a downstream user of a substance or trade association, but could equally be a NGO keen to be involved with the SIEF.⁶³ REACH does not provide for any active role for Data Holders: all the Regulation permits them to do is to supply their data and ask for a share of the cost of its production. ECHA's website does not detail how many Data Providers have made themselves known to it.

Third Party Representatives

In addition, pre-registrants may appoint a so-called "Third Party Representative" (TPRs) to act as an agent on their behalf within a SIEF.⁶⁴ ECHA sees TPRs appointed "typically...when a company wishes not to disclose their interest in a particular substance as this may give indications to competitors about production or commercial secrets."⁶⁵ However, what has happened in practice is that industry associations or consortia leaders have commonly been appointed TPRs on behalf of a number of SIEF members (especially where a SIEF contains members some of whom are linked to a trade association and others who are not). Once appointed, while the TPR represents the pre-registrant at the SIEF, the entity which appoints the TPR remains full legal responsibility for complying with its obligations under REACH.⁶⁶ This is in stark contrast to Only Representatives ('ORs'), who may also be members of SIEFs. As discussed in Chapter 2, an OR may be appointed where the non-EU manufacturer of a chemical wishes to take responsibility for the registration of that chemical out of the hands of the EU based importer. There is now even an Only Representatives Organisation, which seeks to set up OR quality standards and develop commonality of approaches among various ORs.⁶⁷ As the organisation is members only, it is not clear as to the extent of guidance it provides.

Finally, it is also worth noting that different SIEF members may, practically (if not legally), be the same entity. Because REACH requires Registration by each legal

⁶³ ECHA lists various, non-exhaustive, types of data holder in its Guidance on Data Sharing at pages 34-35

⁶⁴ Article 4; Guidance on Data Sharing, 34

⁶⁵ Guidance on Data Sharing, 34

⁶⁶ *ibid*

⁶⁷ See: <www.onlyrepresentatives.org> accessed 10 August 2014

entity which imports or manufactures above 1 tonne per year, this means that a group of EU companies (where each company in the group is a separate legal entity and separately subject to REACH) would need to be represented in the SIEF individually. Using a TPR is a practical way of overcoming this problem.

Lead Registrants

We turn now to the Lead Registrant. Article 11(1) states that, where a substance subject to Registration has more than one manufacturer and/or importer certain information,

“...shall be first submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereafter referred to as ‘the lead registrant’).”

This is the principle of “one substance, one registration”; namely, in order to reduce costs for those subject to Registration, only one registrant need submit the relevant data on behalf of all registrants. While participation in a SIEF is mandatory, the joint submission of registration data via the lead registrant (‘LR’) is not obligatory and registrants have three opt-outs: the first, that joint submission would be too costly;⁶⁸ the second, that joint submission would lead to the disclosure of commercially sensitive information;⁶⁹ and the third, that the registrant disagrees with the LR on the selection of the registration data.⁷⁰ Where registrants do opt out of joint submission, they need to submit their justification for opt out along with their Registration dossier.⁷¹

Save for Article 11(1), REACH is almost silent⁷² about the role of a Lead Registrant⁷² and ECHA comments that the Regulation, “...does not specify rules as to how the Lead Registrant should be selected.”⁷³ This is perhaps somewhat odd as having an efficient and effective LR is one of the key foundations for a SIEF. In ECHA’s Guidance on Registration, the Agency notes that the LR may be registrant with the

⁶⁸ Article 11(3)(a)

⁶⁹ Article 11(3)(b)

⁷⁰ Article 11(3)(c)

⁷¹ Article 11(3)

⁷² Annex VI details that when the Lead Registrant jointly submits data, it should specify the details of the other registrants.

⁷³ ECHA (n 12) 2

highest production volume of the substance but that this is is, “not obligatory.”⁷⁴ The Guidance then notes that, “the joint submission registrants have the possibility to appoint a lead registrant with a lower tonnage.”⁷⁵ The Guidance on Data Sharing, however, comments that the LR, “may be the EU manufacturer or EU importer with the highest interest in registration (e.g. highest tonnage, most data, ...).”⁷⁶ While the two Guidance documents are not contradictory, they do not offer a definitive line of advice for SIEF members. Both documents aim at going beyond the text of the Regulation (and so engage in the amplification function discussed above), but neither is determinative.

Industry associations are similarly vague about LR appointment. Cefic advises that the “main players in industry must consider taking responsibility for the SIEF process and leading the discussions,”⁷⁷ but it does not go so far as to say which entity should shoulder the burden of being LR. Quite aside from the administrative tasks required in being LR, there also comes the corollary potential for liability,⁷⁸ something which can put off certain companies from assuming the LR position.⁷⁹ This lack of definitive guidance for establishing the LR has led to some practical issues and ECHA admits that there are cases of SIEFs with more than one Lead Registrant.⁸⁰ As it has no power to order a company to step down from the LR role (or appoint any particular company to that role), all ECHA can do is advise “communication to decide [the] best LR for the SIEF.”⁸¹ This aspect of REACH is an instance in which the lack of specificity in the Regulation has led to practical issues in the operation of the legislation and in which ECHA has failed to produce definitive guidance for SIEF members.

The preceding discussion has highlighted how SIEFs come into being, SIEF membership and the various roles of those members. This is somewhat complicated.

⁷⁴ Guidance on Registration, 59

⁷⁵ *ibid*

⁷⁶ Guidance on Data Sharing, 40

⁷⁷ Cefic, ‘FAQ on SIEFS’ (April 2009) 7

⁷⁸ For example, the LR could find itself liable for submission of inaccurate or incomplete data for Registration. Or for failing to meet the appropriate Registration deadline. Or for submitting data without having the requisite proprietary rights in relation to that data.

⁷⁹ Wolfmeier (n 16) 3

⁸⁰ Dancet, (n 3) 9

⁸¹ *ibid*

To bring this discussion together, Diagram 5.1 (at the end of this Chapter) depicts the (hypothetical) *jurisite* SIEF, whose members include Data Holders, Only Representatives, Third Party Representatives (representing 1,800 SIEF members from two separate consortia) and ‘ordinary’ Pre-Registrants, as well as the Lead Registrant.

Data Sharing

Having formed a SIEF, selected a structure, allocated roles and decided on a LR, the ‘proper’ work can then begin: namely, the sharing of data. Article 29(3) provides that,

“SIEF Participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies...and arrange for such studies to be carried out”.

As set out in Chapter 3, the amount of data needed to be submitted by a pre-registrant as part of registration depends on two factors: (a) the inherent properties of the substance (with more information needing to be submitted for more harmful substances); and (b) the manufacture or import volumes of the pre-registrant of the particular substance. Given that SIEFs are collections of all pre-registrants of the same substance (with “sameness” the only criteria for inclusion or exclusion), the majority of SIEFs are likely to contain pre-registrants who manufacture or import in different tonnage bands (and so who need to submit different levels of data on different dates). For example, substances manufactured at levels of 10 tonnes or less do not need to submit data on dermal toxicity or in-vitro gene mutation studies in mammal cells, whereas such data is required where the substance is manufactured at levels greater than 10 tonnes.⁸² The issue here is that when SIEF members are sharing data and identifying data gaps, they will each be potentially be driven by different end goals, depending on what REACH requires of them as to the breadth of the data to be submitted for Registration and the deadline for such submission.

‘Go Fish’ and Practical Problems

Aside from Article 29(3), the REACH data sharing provisions are short and promote a style which is reminiscent of the card game “Go Fish”. Article 30 sees individual

⁸² The requisite data for each tonnage band are set out in Annexes VII to X of REACH.

SIEF members asking other members whether a particular data set exists and then, where it does, requesting that data. This request (and subsequent sharing) is mandatory for data involving tests on vertebrate animals and optional for all other data.⁸³ A SIEF member who fails to share data from tests on vertebrate animals is not allowed to proceed with Registration until such sharing occurs.⁸⁴ Imagine this process taking place in the (hypothetical) *jurisite* SIEF:

- (a) SIEF member I sends an email to the other 2,999 member asking if anyone has Study X on invertebrate animals, but no one has Study X;
- (b) then SIEF member II sends an email relating to Study Y on vertebrate animals, which SIEF member CCXI has a copy of and which SIEF member II is then required (Article 30(1)) to request;
- (c) SIEF member III sends an email concerning Study Z on invertebrate animals, which SIEF member XXI has a copy of, although because the study is not on vertebrate animals Article 30(1) says that the requesting company, SIEF member III, then has a choice whether or not to then request a copy of that study (and this process would go on... *ad infinitum*.)

Such a stilted and formulaic process is obviously too mechanical (and inefficient) for the majority of SIEFs. Instead, ECHA advises that,

“In practice, the potential registrants have the task to organise the data sharing activities: i.e. to use more direct forms of cooperation to gather the required information, to agree on the necessary data package and on the classification and labelling, and to prepare for the joint submission of data.”⁸⁵

The use of “In practice” is instructive and suggests ECHA’s awareness of a disconnect between the drafting of REACH and the actual, real world operation of the Regulation. Instead of the stilted approach that is a necessary follow on from the draft of Article 30, the Agency suggests instead what it calls a “collective route” to data

⁸³ Article 30(1)

⁸⁴ Article 30(3)

⁸⁵ Guidance on Data Sharing, 43

sharing.⁸⁶ It is interesting here how the regulator offers SIEF members a particular approach to data sharing which is, in effect, a work around the particular drafting of a particular provision of REACH. This, it is suggested, is another example of ‘translation’, where the Agency, in its guidance, implicitly contests the drafting of the Regulation and ‘translates’ the relevant provisions into something else.

The Collective Route

The ‘collective route’ under ECHA’s Guidance on Data Sharing sees individual SIEF members gathering what data they hold on the substance to be registered, collating and inventorying all the data gathered by all SIEF members, evaluating that information en masse and considering the need for additional data to complete the registration dossier.⁸⁷ In short, the ‘collective route’ promotes a common sense approach to data sharing; one which is supported by Cefic, who recommend that all SIEF members share all relevant data, whether or not obtained from tests involving vertebrates.⁸⁸ The language used and the approach taken in this part of the Guidance on Data Sharing is particularly interesting. ECHA gives SIEF members 17 pages of detailed advice on the 9 steps (not found in REACH) that it sees as forming part of the ‘collective route’. However, the Agency also says that, “The participants of the SIEF are free to organise these steps as they best see fit.”⁸⁹ This tension, between the prescriptive and the permissive, arguably reflects the desire of the Agency to offer guidance to those with obligations under REACH while at the same time being aware of not going beyond its remit. Despite this, the qualifier comes across as somewhat ‘thin’ when compared to the 17 pages of guidance on the “collective route.”

Data Type and Quality

As for the nature of the data to be shared, a strict reading of REACH shows that only hazard based information is obligatory to share (i.e. data on the intrinsic properties of the particular substance).⁹⁰ Other data required for registration (such as data on the

⁸⁶ Guidance on Data Sharing, 45

⁸⁷ Guidance on Data Sharing, 45-61 (with a useful flowchart of the ‘collective route’ at 47)

⁸⁸ Cefic (n 36) 21

⁸⁹ Guidance on Data Sharing, 45

⁹⁰ Articles 25(2) and 29

use of the chemical or studies relating to exposure to the chemical) do not have to be shared. Partly this goes to the notion that certain uses of chemicals will be confidential and, as a consequence, SIEF members should not be forced to share such sensitive information. However, Cefic advises the disclosure and sharing of all data on the substance that may be relevant, save for what they term “exceptional cases of confidentiality”.⁹¹

With existing data that has been shared, SIEF members are given wide ranging discretion to decide on the quality of that data. REACH is silent as to when SIEFs are allowed to discard data that already exists because it is not of appropriate quality. Indeed, REACH is almost silent on the entire issue of quality. In Annex VI of the Regulation, which sets out the broad steps needed to comply with registration obligations, it is observed that (when a decision is taken about data gaps, on which see below), “It is important at this stage to ensure that the available data is relevant and has sufficient quality to fulfil the requirements.” Such decisions about quality and the rejection of data can be very subjective: what company X thinks of Study A may be very different to what company Y thinks of that same study. Given this, Cefic advises that “Efficiency can be highly increased if one qualified SIEF participant, e.g. the lead registrant, or a competent consultant is fulfilling the task of data validation and the other members rely on his/her expertise and judgements.”⁹²

In its Guidance on Data Sharing, ECHA frames the issue of the assessment of data quality through OECD guidance. The Agency notes that, “In line with the OECD guidance, the process of determining the quality of existing data should take into consideration three aspects, namely adequacy, reliability and relevance of the available information, to describe a given study” and goes on to explain each of the aspects in some detail.⁹³ Again, we see tensions between prescription and permission: on the matter of the initial data quality screening of reports, ECHA details that, “two approaches have been proposed by the OECD”, goes on to set out those two approaches but then concludes by noting that, “Other systems [i.e. approaches] may

⁹¹ Cefic (n 36) 39

⁹² *ibid*, 32

⁹³ Guidance on Data Sharing, 96-100

also be considered.”⁹⁴ Given the lack of detailed advice on this issue in REACH and the wish of ECHA to have some sort of uniformity in this area (notwithstanding the qualification noted above), this is another attempt by the Agency at channelling the actions of registrants (and so is a further example of the ‘standardisation’ function of ECHA’s guidance).

Data Gaps

When gaps are identified in the existing data in the possession of SIEF members, there are two options. The first, if the missing data is required to comply with Registration obligations in Annexes VII and VIII, is that the data is generated by the SIEF (or on behalf of the SIEF) and submitted as part of registration. The second, if the missing data is needed to comply with the requirements in Annexes IX and X (i.e. requirements for substances manufactured above 100 tonnes or more), is that testing proposals are created which would generate the missing data;⁹⁵ such proposals are then included as part of the Registration dossier, with ECHA then deciding whether or not such proposals are appropriate.⁹⁶ In order to reduce unnecessary testing, certain instances of “reading across” are permitted. Here, it may be that Chemical A is similar to, but not the same as, Chemical B. Where data is missing for Chemical A, but not for Chemical B, it may be possible to “read across” the data for Chemical B to Chemical A (i.e. to take the data for Chemical B and use it in place of the missing data for Chemical A).⁹⁷

Cost Sharing

Having discussed the sharing of data, we now turn to the sharing of the costs of generating that data. In our (hypothetical) *jurisite* SIEF, let us pretend that one member has a key study that is vital for registration. Although this particular study was undertaken in 1989, the SIEF agrees (going down the ‘collective route’ to data

⁹⁴ Guidance on Data Sharing, 97

⁹⁵ Article 12(1)(e), Article 22(1)(h),

⁹⁶ Article 40(1)

⁹⁷ On when read-across may be permitted, see: ECHA, ‘Guidance on Information Requirements and Chemical Safety Assessment’ (May 2008), Chapter R6 – see:

<http://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf> accessed 10 August 2014

sharing advised by ECHA, discussed above) that the study is still relevant and of the highest quality. In 1989, the study cost the SIEF member £5,000 to perform. Were the same study to be undertaken at the time when the SIEF is debating the issue of data sharing, it would cost £50,000 to perform. Given this, how should the study be valued and the SIEF member compensated for sharing the study with the other members: on the basis of the historic cost or on the basis of the cost to replace the study? All that REACH says is that SIEF members, "...shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way."⁹⁸ While ECHA does not, in its guidance, prescribe a particular method of calculation, its advice has changed over time. In 2007, the (then) Guidance on Pre-Registration and Data Sharing stated that, "Which of those two methods (historic costs or replacement costs) is more appropriate is a matter for discussion within the SIEF."⁹⁹ The current Guidance on Data Sharing, however, now states that, "Nothing prevents the potential registrant(s) from agreeing on valuation methods, such as the "replacement value", i.e. the price that would be paid today to obtain the same study."¹⁰⁰ This shift, it is suggested, sees ECHA placing greater emphasis on the 'replacement value' approach as valid.

There are 20 pages of guidance on cost sharing in the Guidance on Data Sharing, detailing specific factors (sales volumes, production volumes etc) that could be taken into account and offering up 10 worked out examples of study cost allocation.¹⁰¹ This guidance is specifically provided for in the text of REACH, where Article 30(1) says that SIEF members,

"shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 77(2)(g)."

Where agreement cannot be reached on cost sharing, the default (in Article 30(1)) is equal allocation. Cefic, meanwhile, promotes (but does cross over the line into

⁹⁸ Article 30(1)

⁹⁹ ECHA, Guidance on Pre-Registration and Data Sharing (Version 1.0, 2007 – copy on file with the author) 73

¹⁰⁰ Guidance on Data Sharing, 100

¹⁰¹ Guidance on Data Sharing, 100-110

actually recommending) the compensation-free sharing of existing data.¹⁰² While ECHA provides detailed guidance on costs sharing, it is not, it is suggested, attempting to favour one model of cost sharing over another. Given this, it is submitted that this guidance is simply amplifying the text of REACH.

In the (hypothetical) *legale* SIEF, each manufacturer produces between 1 and 10 tonnes of the substance each year. In the (hypothetical) *jurisite* SIEF, of the 3,000 members, some produce over 1,000 tonnes per year of the substance (given the heavy powdering of judges' wigs); some produce between 10 and 100 tonnes per year; some produce between 100 and 1,000 tonnes per year and others produce between 1 and 10 tonnes. Here, depending on the tonnage band of manufacture, each pre-registrant will have different obligations as regards the information necessary for Registration. Some will have registered in 2010; others in 2013; others in 2018. This has implications for the sharing of costs: what should one member (who produces only 5 tonnes per year and does not need to register until 2018) have to pay compared to another (who produces 2,500 tonnes per year and registers in 2010)? Here, the Cefic standard form SIEF agreement gives three options for costs sharing.¹⁰³ The first involves a calculation of costs before each registration deadline with all costs shared by the 2010 registrants; there is then a recalculation in 2013 and 2018 with appropriate refunds to the 2010 registrants. The second sees the 2010 registrants making a 50% advance payment on a "best estimated costs" basis (with the balance payable at the moment of joint submission); the 2013 and 2018 registrants make their payments (with no refund). The third option is an equal lump sum payment for all registrants at the beginning of the SIEF process. ECHA, in the Guidance on Data Sharing, does not provide this level of specificity in its cost allocation advice.

A less than obvious matter turns on the costs of cost sharing. Where the sharing of a particular study is contentious and great time is spent by the SIEF debating how costs should be shared in relation to that study, the cost of that debate may outweigh the cost of the study itself. Given this, Cefic advises that, "...careful consideration should

¹⁰² Cefic (n 36) 37

¹⁰³ <<http://cefic.org/templates/shwPublications.asp?HID=750&S=33>> accessed 10 August 2014

be given to the application of any cost sharing mechanism to avoid that more resources are spent on sharing the costs than are gained by compensation.”¹⁰⁴

Conclusions

Getting pre-registrants together and compelling them to share data in a SIEF is one of the core purposes of REACH. Given this, the lack of specificity on SIEFs in the text of the Regulation is striking. Wide discretion is given to pre-registrants as how a SIEF is formed, what format the SIEF takes and how it operates (membership, roles, data evaluation, cost sharing etc). It is probably fair to say that those who drafted REACH did not expect the level of administrative architecture created by SIEFs (pre-SIEFS and consortia) as has happened to date. An entire industry of SIEF management has been created off of the back of the Regulation. The topography of each SIEF will vary considerably: some will amount to small groupings of specialist chemical manufacturers, where each SIEF member has some parity of input and contribution; others will contain thousands of members, be ran by a small core of manufacturers and importers and may ‘drag’ other participants along with them; others still will be barely functioning, non-distinct groups of competitors unable or unwilling to cooperate and agree.

REACH makes collaborative self-regulation mandatory for certain matters (namely, being a member of a SIEF) but in others (for example, opting out of joint submission) companies are allowed to go it alone. This disconnect is odd, especially given the principle of ‘one substance, one registration’ which is said to underpin the Regulation. There is also something discordant in letting the private sector order itself so fully as the foundation of the EU’s chemical regime. In short, SIEFs are independent of ECHA (and of REACH) and yet are critical to the effective functioning of the Regulation.

This independence is, however, shaped by the guidance produced by ECHA relevant to SIEFs, namely the: (a) Guidance on Data Sharing; (b) Guidance on Information Requirements and Chemical Safety Assessment (discussed more fully in the

¹⁰⁴ Cefic (n 36) 37

following Chapter); and the (c) Guidance for Identification and Naming of Substances. In addition, ECHA has produced two User Manuals which assist registrants with the IT aspects of SIEF formation and data sharing. Of all the elements of REACH, the creation and running of SIEFs is *the* area in which guidance produced by ECHA amplifies the text of the Regulation, channels the day to day operation of the legislation via standardising the behaviours of pre-registrants and, in more limited circumstances, breaks away from the provisions of the legislation. There are also examples in this area of ECHA cementing gaps in the Regulation through its guidance. It is submitted that without this guidance, data generation, assessment and sharing under REACH would fail. However, the impact of ECHA's guidance is variable. The level of amplification, standardisation and translation differs between ECHA guidance documents and between different aspects of the operation of REACH.

In the context of amplification, this Chapter has highlighted a number of instances in which ECHA's guidance has built on provisions in REACH: in how registrants assess the quality of the data they hold; in how costs of sharing might be shared among registrants; and in the role and functioning of 'Data Holders'. Here, the Agency is not engaged in forcing registrants down any particular course of action, but instead is offering what might be thought of 'pure' advice on the text of REACH. In contrast, this Chapter has also highlighted a number of areas in which ECHA, in its guidance, does express (albeit often implicitly) a preference for how the operationalisation of the Regulation should work: in the processes the Agency suggests for determining chemical "sameness"; in the detailed advice on consortia and provisions in consortia agreements; and in the use of independent third parties to avoid falling foul of competition law. These latter examples, I would suggest, demonstrate the standardisation function of ECHA's guidance.

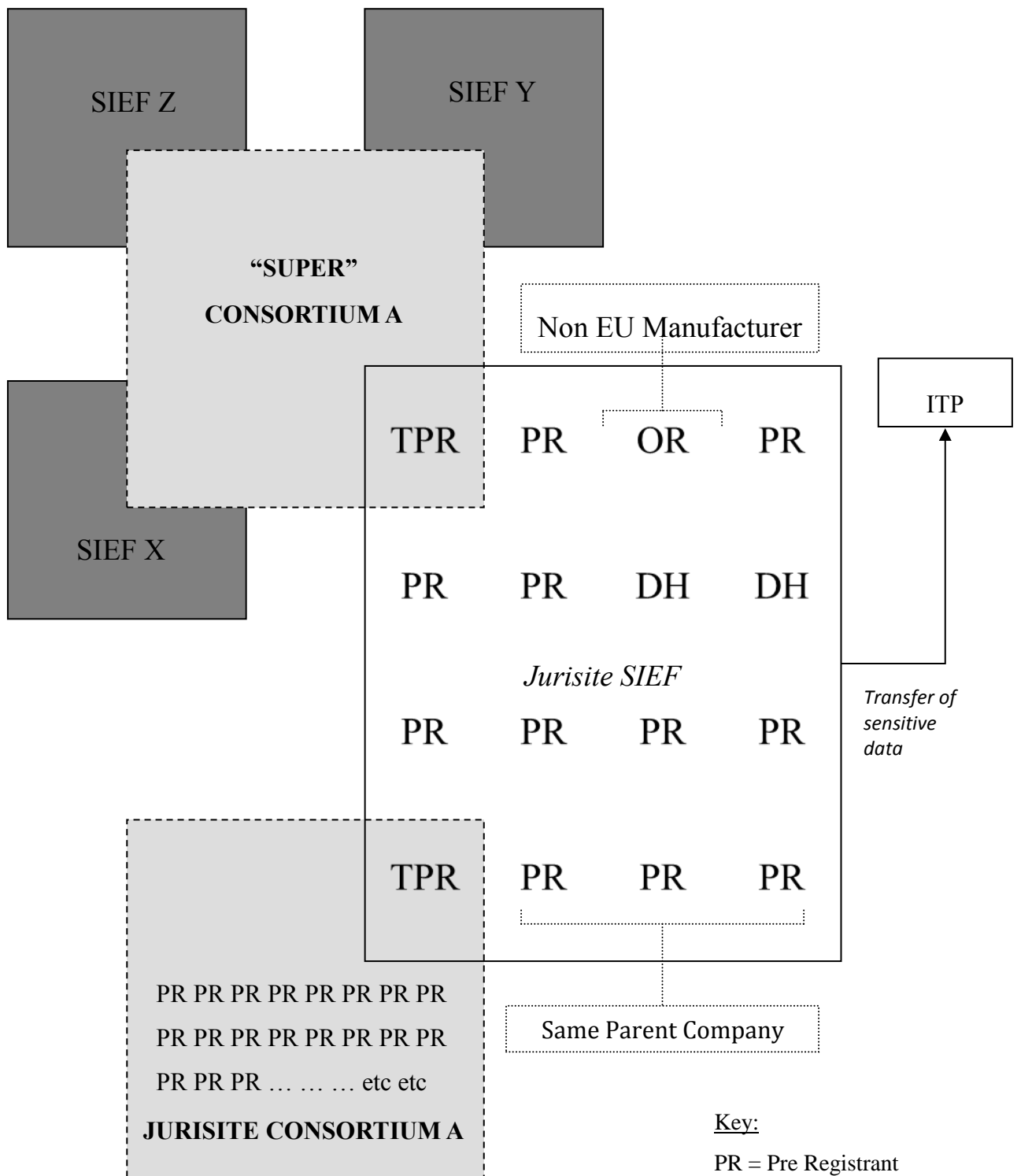
In two instances, ECHA's guidance stands in stark contrast to the text of REACH: on the issue of exactly when a SIEF is formed; and on how a SIEF member should go about the mechanics of data sharing (i.e. the "collective route" as opposed to 'Go Fish'). These examples, it is suggested, demonstrate the 'translation' function of the guidance: where ECHA does not (for whatever reason) like how the Regulation could be read, and so sets out its views in other words.

Away from ECHA, this Chapter has also explored the shaping of SIEFs via guidance produced by trade associations. Cefic, for example, has 83 individual REACH guidance documents or tools, of which 19 touch on the formation and operation of SIEFs. These trade associations, and the guidance they provide, add another layer of post legislative norm elaboration for REACH. Similarly, the power of consortia agreements to act as a form of regulatory control is also striking. Their drafting shapes the parameters of how companies will respond to REACH and yet fall without traditional accounts of hard and soft law.

These four functions of ECHA's guidance on data sharing and substance identification (amplification; extrapolation; standardisation; and translation) are seen, to varying degrees, in ECHA's other guidance documents. These are highlighted in the following three Chapters. What is worth emphasising is that not every guidance document has the same type or level of impact and not every one of the above four functions is seen in every one of those guidance documents. This makes understanding what ECHA's guidance actually does both interesting and challenging. In exploring REACH through the lens of the Regulation and of its associated guidance, the "complex normativity" that Scott highlighted of this regulatory response to chemicals risk management becomes even more complex.¹⁰⁵ Having reviewed the creation and functioning of SIEFs, the Chapter which follows explores various aspects of REACH which relate to information exchange, transmission and disclosure upwards from registrants to ECHA and beyond.

¹⁰⁵ Joanne Scott, 'REACH: Combining Harmonisation with Dynamism in the Regulation of Chemicals' in Joanne Scott (ed.), *Environmental Protection: European Law and Governance* (OUP 2009) 59

DIAGRAM 5.1



Key:
 PR = Pre Registrant
 OR = Only Registrant
 TPR = Third Party Representative
 ITP = Independent Third Party
 DH = Data Holder

CHAPTER 6

REGISTRATION, EVALUATION AND THE WIDER ROLE OF INFORMATION UNDER REACH

Information generation and disclosure form the heart of REACH. Expressly created to address a data deficit within the EU on the intrinsic properties of chemicals, the underpinning basis of the Regulation is that information on these chemicals is key and should be generated by the private sector (before transmission to regulatory bodies where it then becomes available to the wider public). The stated aim is that greater information on the intrinsic properties of chemicals will lead to more effective management of the risks from those chemicals (risks which will be ‘known’ following the information generation process).¹ Two matters are worth stating at the outset. The first is that the relationships created under the REACH provisions on information generation and disclosure are not linear. It is not simply a case of chemical producers feeding information up to the regulator. Instead, there are a series of interconnected and at time overlapping streams of information which pool (and occasionally stagnate) at different points. The second is that creating and having information only goes so far: a large part of whether or not regulating by information is effective turns on the quality of the information produced, the capacity of any regulator to evaluate the information and the ability of third parties (consumers, NGOs etc) to understand and act on that information. These themes underpin this Chapter and those that follow.

This Chapter explores various aspects of REACH which relate to information exchange, assessment, transmission and disclosure. These take four broad forms (although it is important to note that the information provisions within REACH are spread throughout the Regulation and are not explicitly grouped as in this Chapter): the first relates to the transmission of chemical testing data to ECHA and the subsequent dissemination of that data; the second concerns the right of ECHA

¹ Commission, ‘White Paper on the Strategy for a future Chemicals Policy’ COM (2001) 88 final

to evaluate the data it receives; the third relates to rights granted to third parties to call for or be provided with information on chemicals contained within articles; and the fourth touches on third party (i.e. non-registrant, non-supplier) information obligations.

Supplementing the text of the Regulation on these matters are seven guidance documents (though arguably all of the guidance produced by ECHA concerns, in some way, chemicals data): (a) Guidance on Registration;² (b) Guidance on the Communication of Information on the Risks and Safe use of Chemicals;³ (c) Guidance on Requirements for Substances in Articles;⁴ (d) Guidance on Information Requirements and Chemical Safety Assessment;⁵ (e) Guidance on the Compilation of Safety Data Sheets;⁶ (f) Guidance on Dossier and Substance Evaluation;⁷ and (g) Guidance on Priority Setting for Evaluation.⁸ These documents are discussed in further detail throughout this Chapter. However, what is striking is that of all the elements of REACH, data transmission and dissemination receive the least attention in the guidance documents produced by ECHA. Data creation is another matter, as was seen in Chapter 5. What is also striking about these guidance documents is that they are largely dense and technical. To date, ECHA has not produced guidance to assist in the translation of complex chemical data to third parties, in particular to the wider public who have

² ECHA, ‘Guidance on Registration’ (Version 2.0, May 2012) – hereafter the ‘Guidance on Registration.’ See: <http://echa.europa.eu/documents/10162/13632/registration_en.pdf> accessed 10 August 2014

³ ECHA, ‘Guidance on the Communication of Information on the Risks and Safe use of Chemicals’ (Version 1, December 2010). See: <http://echa.europa.eu/documents/10162/13639/risk_communications_en.pdf> accessed 10 August 2014

⁴ ECHA, ‘Guidance on Requirements for Substances in Articles’ (Version 2, April 2011). See: <http://echa.europa.eu/documents/10162/13632/articles_en.pdf> accessed 10 August 2014

⁵ ECHA, ‘Guidance on Information Requirements and Chemical Safety Assessment’ (Part A, Version 1.1, December 2011). See: <<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>> accessed 10 August 2014

⁶ ECHA, ‘Guidance on the Compilation of Safety Data Sheets’ (Fourth Draft, July 2011). See: <http://echa.europa.eu/documents/10162/13563/fourth_draft_sds_guidance_july_2011_en.pdf> accessed 10 August 2014

⁷ ECHA, ‘Guidance on Dossier and Substance Evaluation.’ This document, once housed on the ECHA website, is now said to be “obsolete” and has been removed: see - <<http://echa.europa.eu/guidance-documents/guidance-on-reach>> accessed 10 August 2014. The author has a hard copy of this guidance on file. Copy on request.

⁸ ECHA, ‘Guidance on Priority Setting for Evaluation.’ This document, once housed on the ECHA website, is now said to be “obsolete” and has been removed: see - <<http://echa.europa.eu/guidance-documents/guidance-on-reach>> accessed 10 August 2014. The author has a hard copy of this guidance on file. Copy on request.

‘rights to know’ under REACH. This disconnect is also explored in more depth below.

By way of introductory overview to the elements of REACH discussed in Chapter 3, manufacturers and importers submit information on the intrinsic properties of chemicals to ECHA through the process of Registration. This information is, in part, then made publicly available and is also transmitted along the substance supply chain and to employees. Some of the data which ECHA receives is evaluated by the Agency, but most is not. Consumers have the right to ask for information from suppliers on whether the ‘articles’ (essentially, products) they own contain substances “of very high concern” which have been prioritised for potential regulatory action (namely, Candidate List substances).⁹ Such information is also required to be disclosed (without the need for request) to ‘industrial’ customers (i.e. non consumers) of such articles. Here, the information provisions in REACH can be split between those which apply to substances per se and those which apply to articles (in which certain substances are present). In addition, downstream users of chemicals, other actors in the supply chain, Member States, ECHA and the Commission each have a variety of obligations under REACH to either notify various parties of certain chemical information or to report on their activities. These elements are brought together in Diagram 6.1 at the end of this Chapter.

Transmission and Dissemination of Testing Data

The Substance Dossier

As a starting point, manufacturers and importers of substances subject to REACH are required to provide to ECHA a dossier of information on that substance as part of the Registration process¹⁰. The contents of the dossier depends on the tonnage band in which the substance is manufactured or imported (more than 1,000 tonnes per year; more than 100 tonnes but less than 1,000 tonnes per year etc). For all chemicals, a “Technical Dossier” is required as part of Registration. For chemicals

⁹ On which, see Chapter 7

¹⁰ Article 6; Article 10

manufactured or imported in quantities greater than ten tonnes per year, a “more formal”¹¹ “Chemical Safety Report” is required in addition to the Technical Dossier.¹²

The broad contents of the Technical Dossier are set out in Article 10(a) (and more particularly in Annex VI) which requires the submission of the following data:

- (i) the identity of the manufacturer(s) or importer(s);
- (ii) the identity of the substance;
- (iii) information on the manufacture and use(s) of the substance;
- (iv) the classification and labelling of the substance;
- (v) guidance on safe use of the substance;
- (vi) study summaries of the information derived from the application of Annexes VII to XI;
- (vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;
- (viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;
- (ix) proposals for testing where listed in Annexes IX and X; and
- (x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI.

As noted above, the relative breadth of information needed to be included in the Technical Dossier varies as a function of the tonnage in which the substance is manufactured or imported. The higher the tonnage, the more information Annexes VI to XI of REACH require to be included on the intrinsic properties of the substance. On a general basis, most of the information to be submitted relates to the intrinsic properties of the substance. What this means is that the information should detail how and to what extent the chemical impacts, or has the potential to impact, on the environment and human health: Is it carcinogenic or toxic?; Does it

¹¹ Guidance on Registration, para 1.3

¹² Article 14(1)

persist in the environment? etc. Where a Chemical Safety Report is required, this details the human health and environmental hazards posed *as well as* an assessment of exposure and risk. Risk and exposure assessments are only required for certain chemicals, namely those which, as a result of the hazard assessment, meet the criteria for classification as dangerous in accordance with the CLP Regulation or which are assessed as persistent, bioaccumulative or toxic (“PBT”) or very persistent or very bioaccumulative (vPvB). On a practical level, the registration dossier needs to be submitted using a REACH specific software application known as IUCLID (the International Uniform Chemical Information Database).¹³

The production of data on the intrinsic properties of chemicals is the heart of REACH. Given this, it is not surprising that ECHA has produced detailed guidance to assist registrants with their obligations. The Guidance on Information Requirements and Chemical Safety Assessment is the most dense and most technical of all that published by ECHA. It is in fact 28 separate guidance documents, amounting to more than 200,000 words of text across 2,232 pages.¹⁴ These 28 are (implicitly) addressed to chemists and regulatory scientists and detail processes for chemicals data collection and assessment, the identification of data gaps and the subsequent generation of additional data to fill those gaps. The more accessible Guidance on Registration is written for those “with or without expert knowledge in the field of chemicals” and acts as an umbrella overview of the implementation of REACH.¹⁵ This guidance document details helpful examples and the language used is markedly different (namely, more layperson friendly) than that used in the Guidance on Information Requirements. The Guidance on Registration takes the text of REACH and puts it into more accessible language. Without these two documents, REACH would still operate, in the sense that the legislative framework found in the Regulation is, in this area (chemicals testing), sufficiently detailed for registrants to comply with their obligations without further support. However, the complexity and depth of the Guidance on Information Requirements is an obvious attempt to bring some standardisation to chemicals

¹³ Article 111

¹⁴ ECHA (n 5)

¹⁵ Guidance on Registration, 11

assessment and to channel registrants down good practice avenues. This in turn provides benchmarks by which ECHA can assess the quality of the data submitted to it and, as a corollary, should allow for comparisons between chemicals. However, ECHA has found the quality of information submitted to it to be variable and, on many occasions, inadequate. Both the 2011 review of REACH by ECHA and the 2012 review of the Regulation conducted by the Commission highlighted the poor quality of much of the information that had been created.¹⁶

The Registration requirement to transmit data to ECHA is not a once and for all time information communication obligation. Rather, REACH contains various provisions concerning when the dossier held by ECHA on a substance needs to be updated. Article 22(1) provides that registrants are to update their dossiers “without undue delay with relevant new information”. Here, “relevant new information” includes, among other matters, “new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report”.¹⁷ An update is also required for a “change in...status” of the registrant,¹⁸ which is of importance on corporate finance transactions on the asset transfer of a business which is a REACH registrant.

The ECHA ‘Library’

Article 77(2) obliges ECHA’s Secretariat to make certain information provided to ECHA in Registration dossiers available to the public free of charge over the internet.¹⁹ This information can be found on a subsection of the ECHA website.²⁰ The overriding aim with dissemination to the public of information on chemical properties is to grant the public, “free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labelling requirements and relevant Community legislation including authorised uses and

¹⁶ *ibid*, 102; European Chemicals Agency, *The Operation of REACH and CLP* (ECHA-11-R-003-EN, 2011) 24

¹⁷ Article 22(1)(e)

¹⁸ Article 22(1)(a)

¹⁹ The exact information to be provided is listed in Articles 119(1) and (2) but amounts to a large proportion of the registration dossier.

²⁰ See: <<http://apps.echa.europa.eu/registered/registered-sub.aspx>> accessed 10 August 2014

risk management measures”.²¹ As an aim, this is laudable and ECHA’s Management Board have stated that they consider the dissemination of registration information a “cornerstone of REACH and vital for achieving the REACH goals”.²² However, such dissemination is beset by the following four foundational issues, each of which will be discussed in turn: (a) what is there is not useful in any really meaningful way for the public; (b) what is there has likely never been checked for quality; (c) some information might be missing; and (d) some of the information might be contradictory.

On the question of utility, data on the ECHA website which the public may access relates only to substances (and does not, for example, relate to the end products which contain those substances). As ECHA puts it, “In other words, you can find information about methanol or butane, but not for example about a shampoo, cleaning product or pencils”.²³ Given that few members of the public regularly purchase isolated chemicals (as opposed to mixtures of chemicals or products in which chemicals are contained or in whose production chemicals have been used), it is questionable how useful this information really is. It also questionable whether, as a matter of fact, any members of the public would ever access the database to look up specific chemicals. What may be more likely, however, is that specialist NGOs and other third party organisations would actively interrogate the ECHA database for data on chemicals of concern to them.

The issue of utility also goes to the *content* of the information that is made public. Given the data disseminated on ECHA’s website comes from substance registration dossiers, it is necessarily technical in nature and there is no obligation in REACH for registrants to provide non-technical summaries of their

²¹ Recital 117

²² Antonello Lapalorcia, ‘The Importance of Dissemination’ (ECHA Stakeholder’s Day Speech, 2010) – see: <http://echa.europa.eu/doc/press/events/stks_day_20100519/importance_of_dissemination_antonello_lapalorcia.pdf> accessed 10 August 2014

²³ ECHA, ‘Questions and Answers about ECHA’s public database with information on registered substances’ (webpage) – see: <<http://echa.europa.eu/support/faqs/q-and-a-about-echas-public-database-with-information-on-registered-substances>> accessed 10 August 2014

registrations.²⁴ Let us take the substance N-(2,6-dimethylphenyl)pyridine-2-carboxamide as an example (as this was the first substance on a search of the ECHA website for all registered substances).²⁵ The ‘dossier’ for this substance available to the public is set out in five headings: (i) General Information; (ii) Classification and Labelling; (iii) Manufacture, Use and Exposure; (iv) Guidance on Safe Use; and (v) Reference Substances.²⁶ Many of the subsections for these (such as “Biocidal Information” and “Exposure Estimates”) contain no information whatsoever (and there is no commentary or other guide to indicate why this is so or what this lack of data means); and those that do contain information are weak as regards public access and usefulness. For example, in the subsection on “Classification and Labelling”, there is the remark “Caution – substance not yet fully tested”, although the same subsection also contains the data that the substance is “harmful if swallowed...irritating to eyes and skin...[and] harmful to aquatic organisms”. The foregoing somewhat goes against the comment by ECHA that the public availability of chemical information will, “allow [consumers] to make fully informed decisions about their use of chemicals”.²⁷ It may be (as noted above) that the public availability of chemical data under REACH will allow NGOs with specialist employees or other third parties with a consumer agenda to access and evaluate chemical properties, but such seems remote for the average member of the public. It is also worth noting how limited any consumer recourse might be in pursuing a complaint regarding information housed on ECHA’s website. Thus the determination of the configuration of the website and its contents may lie some distance from the formal requirements of Article 77.

The second foundational issue with the data made publicly available on the ECHA website goes to the quality of that data. As detailed in Chapter 3, only 5% of all registration dossiers will be Evaluated. For the rest, as long as the dossier passes

²⁴ Unlike, for example, in European Union legislation on environmental impact assessments of certain developments – see Council Directive (EC) 85/337 on the assessment of the effects of certain public and private projects on the environment [1985] OJ L 175

²⁵ Search performed on 1 July 2010 (and rechecked on 10 August 2014)

²⁶ See: <http://apps.echa.europa.eu/registered/data/dossiers/DISS-76fd30e3-f86b-2690-e044-00144f26965e/DISS-76fd30e3-f86b-2690-e044-00144f26965e_DISS-76fd30e3-f86b-2690-e044-00144f26965e.html> accessed 10 August 2014

²⁷ ECHA (n 23)

the “completeness check” (i.e. as long as all the boxes in the Registration dossier template are filled in with something, whatever that something might be), there will be no evaluation of content or other form of review by a regulatory agency.²⁸ ECHA therefore does “not guarantee the correctness or adequacy of the information or that the dossiers are compliant with REACH”.²⁹ Given this, a consumer looking at a dossier on the ECHA website has little by way of comfort as to the accuracy of the data they are reviewing. As noted above, the likelihood is that much of the data they see is of questionable quality. Given the robust nature of the guidance produced by ECHA on the generation of chemicals data (discussed in Chapter 5) there is then a disconnect between policy and practice. We might then ask how the provisions in REACH (and the associated guidance) are enforced. This is explored in Chapter 8.

Not all data sent to ECHA as part of a Registration dossier for a substance necessarily appears on the ECHA website and is available to the public. Article 10(a)(xi) details that, as part of Registration, a registrant may also submit,

“a request as to which of the information in Article 119(2) [i.e. that information which would ordinarily be disclosed on the ECHA website] the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.”

Thus, registrants may request that certain data is not published on what effectively amounts to grounds of business confidentiality. Matters which are “normally...deemed to undermine the protection of commercial interests” are set out in Article 118(2) as follows:

- “(a) details of the full composition of a preparation;
- (b) without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;
- (c) the precise tonnage of the substance or preparation manufactured or placed on the market;
- (d) links between a manufacturer or importer and his distributors or downstream users.”

²⁸ Obviously, it would be open to third parties to review the quality of registration dossiers and to then report back to ECHA, the Commission and/or Member State competent authorities. However, the author is not aware of this having taken place to date.

²⁹ ECHA (n 23)

For the public, there is also the issue of the ECHA website hosting different data on the same substance. Information is displayed per registration. As is detailed in Chapters 3 and 5, under certain situations, registrants of the same substance are allowed to depart from the “one substance, one registration” principle and submit separate registration dossiers for the same substance. ECHA comments that “the separate submission of data may result in the display of several entries in the database”,³⁰ but does not go on to state that these entries may contain substantially different information of the intrinsic properties of the same substance and that, for the average member of the public, understanding which of the registrations may have the ‘right’ data would be all but impossible.

Information Dissemination Outside the EU

Article 120 empowers ECHA to disclose information received by it to certain governments of “third countries” and international organisations in specific situations.³¹ Information may be disclosed by ECHA notwithstanding it may otherwise be afforded protection under Articles 118 and 119 of REACH (i.e. it might undermine commercial interests), although there are two criteria for disclosure, as follows: (a) the purpose of the agreement must be cooperation on the implementation or management of legislation concerning chemicals covered by REACH; and (b) the third party must protect confidential information as mutually agreed.

Information Communication by Member States

Article 123 states that, “the competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment.” This

³⁰ ECHA (n 23)

³¹ This is either in accordance with: (i) Article 212 TFEU (formerly Article 181a(3) of the EC Treaty), which states that, “Within their respective spheres of competence, the Community and the Member States shall cooperate with third countries and the competent international organisations”; or (ii) or under an agreement concluded between the Community and the third party concerned under Council Regulation (EC) 304/2003 concerning the export and import of dangerous chemicals [2003] OJ L 63/1 (as amended)

is a good example of a framework norm under REACH in which the Regulation explicitly sees (and commands) the need for further elaboration via guidance:

“The Agency, in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice, shall provide guidance for the communication of information on the risks and safe use of chemical substances, on their own, in mixtures or in articles, with a view to coordinating Member States in these activities.”³²

The document produced by ECHA, Guidance on the Communication of Information on the Risks and Safe Uses of Chemicals, amounts to 68 pages or 23,924 words.³³ Addressed to Member States (and the regulatory bodies therein responsible for chemicals, ‘MSCAs’) the caveat in the introduction to the guidance is instructive:

“Most, if not all, Member States will have some existing systems in place for communicating about the risks of chemicals. Therefore, this guidance is intended to be a manual of practical relevance for those with less experience to enable them to carry out necessary risk communication effectively and a starting-point for further reference for others. It is not intended to *prescribe* to all MSCAs how to carry out risk communications [emphasis as in the original].”³⁴

When the guidance is read, the reasons for these caveats become obvious. What is set out is both basic and generic. For example, ECHA comments that risk communication helps to build trust with the public and that it is important that effective working relationships be built up with people that will need to be involved in the future.³⁵ Much of what is written is also suggestive: MSCAs are advised to “consider” doing X or Y on 59 separate occasions in the guidance. There is a sense that the Agency was trying to spell out minimum requirements on risk communication for those Member States without a history of public engagement on chemicals while at the same time placating other Member States where there are a variety of different approaches. This guidance, it is suggested, is an example of ECHA amplifying the text of REACH. What is also striking about this guidance is that this guidance on risk communication is addressed to Member States; there is not a comparable guidance document addressed to

³² Article 123

³³ ECHA (n 3)

³⁴ *ibid*, 6

³⁵ ECHA (n 3) 13 and 22

registrants/industry. This is despite the fact that REACH requires pro-active communication along the supply chain and re-active data dissemination to the wider public. These aspects are discussed in the sections that follow.

Supply Chain Communication on Substances

Prior to REACH, “safety data sheets” (“SDS”) were used by industry to communicate risks relating to the use of chemicals along a supply chain. Given this practice, it was thought appropriate to expand their use, making them an “integral part” of the Regulation.³⁶ Under Article 31(1), a SDS is required to be provided, free of charge on paper or electronically,³⁷ and in an official language of the Member State(s) where the substance or preparation is placed on the market,³⁸ by the supplier of a substance meeting one of the following classification criteria: (a) “dangerous”; (b) PBT or vPvB; or (c) on the Candidate List. Though this is an obvious point to make, the supplier of a substance may not be the same person or entity as its manufacturer or importer (and so these provisions cast the net of REACH information obligations wide). The content and format of the SDS are set out in Annex II, with further elaboration via the 125 pages of the Guidance on the Compilation of Safety Data Sheets document produced by ECHA.³⁹ Broadly, the SDS should describe, document and notify in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance for which a SDS is required.⁴⁰ In other situations, the recipient of a substance may request a SDS notwithstanding the lack of positive obligation in Article 31(1) to provide a SDS (e.g. for a substance for which there are Community workplace exposure limits).⁴¹ SDSs are to be updated without delay on the occurrence of certain events (e.g. a restriction for that substance is imposed).⁴²

³⁶ Recital 57

³⁷ Article 31(8)

³⁸ Article 31(5)

³⁹ ECHA (n 6)

⁴⁰ Recital 25

⁴¹ Article 31(3)

⁴² Article 31(9)

Even where there is no obligation to provide a SDS, a supplier must still furnish the recipient of a registered substance with certain limited information: namely, the substance's registration number, details of any authorisation or restriction and "any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied."⁴³ Such information is to be provided "at the latest at the time of the first delivery of a substance on its own or in a preparation after 1 June 2007,"⁴⁴ and, as with the SDS, this is free of charge and needs to be updated on the occurrence of certain events.⁴⁵

While Articles 31 and 32 of REACH may seem detailed (with further specifics set out in Annex II of the Regulation), it is the associated guidance document that provides the real specificity of exactly how a SDS should be compiled, who should compile it and what competencies the author of the SDS should have.⁴⁶ The guidance also helpfully puts the SDSs required under the Regulation in context and explains how they differ to the SDSs required pre-REACH.⁴⁷ As with the Guidance on Information Requirements discussed earlier in this Chapter, the Guidance on the Compilation of Safety Data Sheets aims at standardisation of approach and at channeling registrants down a particular course of action. Without the guidance, SDSs would still be produced and would still need to comply with Annex II of the Regulation and would, broadly, contain similar information but it is likely they would look very different. As well as standardisation, the Guidance on Compilation of Safety Data Sheets also amplifies the text of REACH. For example, Annex II of the Regulation details that the SDS should be produced by a "competent person". This term is not defined in REACH. However, the Guidance sets out that a "competent person" is:

"a person (or combination of persons) – or a coordinator of a group of people - who has or have, as a result of their training, experience and continued education, sufficient knowledge for the compilation of the respective sections of the SDS or of the entire SDS."⁴⁸

⁴³ Article 32(1)(d)

⁴⁴ Article 32(2)

⁴⁵ Article 32(2), Article 32(3)

⁴⁶ ECHA (n 6) 2

⁴⁷ *ibid*, Chapter 2

⁴⁸ ECHA (n 6) 12

With the above example, the guidance is not prescribing a suggested or possible course of action, but is instead simply building on the framework of REACH. This, it is suggested, is the key difference between the standardisation and amplification functions of the guidance produced by ECHA.

The Guidance on the Compilation of Safety Data Sheets further details that the supplier of the SDS can delegate the role of “competent person” to a third party and that there should be continuing education and training of whoever takes on the role.⁴⁹ The third function of this Guidance is extrapolation. Take for example the obligation in Article 31(5):

“The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or preparation is placed on the market, unless the Member State(s) concerned provide otherwise.”

One could argue that the use of “the Member State(s) concerned” is ambiguous. However, the Guidance makes it clear that,

“it is for the recipient Member State (MS) to provide otherwise – for example the existence of an exemption in the MS of manufacture does not give an exemption in a different MS where the substance or mixture is placed on the market”⁵⁰

and in so doing extrapolates meaning where the text of REACH is lacking.

Access to information for workers

Articles 31 and 32 detail how information flows from suppliers to purchasers. Article 35 sees this information flow outwards and provides that workers and their representatives are to be “granted access” by their employer to the information provided in accordance with Articles 31 and 32 (i.e. data provided in a SDS or other information provided on a substance or preparation) in relation to substances or preparations that they use or may be exposed to in the course of their work. Exactly what it means to “grant access” is not clear. The Guidance on the Compilation of Safety Data Sheets is oddly quiet on this matter and simply states:

“The SDS (in the EU) is aimed at the employer. The employer has a responsibility to transform the information into suitable formats to manage risks at the specific workplace. Nonetheless access must be

⁴⁹ *ibid*

⁵⁰ ECHA (n 6) 19

given to relevant SDS information to workers and their representatives according to Article 35 of REACH.”⁵¹

As discussed in more depth below, while guidance produced by ECHA is detailed when it comes to business to business communication or technical matters, there is little which speaks to risk communication by registrants and suppliers with employees or the general public. As a consequence, this means that the extent to which the hard law bricks of REACH are joined together by the soft law mortar of guidance is a matter of great discretion.

Evaluation – The Assessment of Data Submitted to ECHA

Once a registration dossier is received by ECHA, it is assigned a registration number, for the purposes of identification.⁵² A ‘completeness check’ is then undertaken. As set out in Chapter 3, this is essentially a box checking exercise to see if any of the elements required for registration are missing. This check does not look at the quality of the data being submitted. It simply checks whether the right types of data have been included. The completeness check is required to be undertaken within three weeks of submission of registration and, where such check highlights incomplete or missing data from a registration, the registrant will be informed of this by the Agency and given a “reasonable deadline” to submit an amended, hopefully complete, registration.⁵³

After registration (and a successful completeness check), ECHA will then evaluate (or assess) a certain number of registration dossiers and registered substances. The recitals to REACH detail that evaluation is said to be required in order to,

“...instil confidence in the general quality of registrations and to ensure that the public at large as well as all stakeholders in the chemicals industry have confidence that natural or legal persons are meeting the obligations placed upon them.”⁵⁴

On its website, ECHA comments that the Member States and the Agency evaluate the information submitted by companies, “to examine the quality of the

⁵¹ ECHA (n 6) 22

⁵² Article 20(1)

⁵³ Article 20(2)

⁵⁴ Recital 65

registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment.” As will be seen below, the actual amount of evaluation that goes on means this statement may be somewhat disingenuous.

The Evaluation processes under REACH are split into two parts: (a) dossier evaluation; and (b) substance evaluation. The relevant provisions can be found in Title VI of the Regulation, Articles 40 to 54 inclusive. In June 2007, ECHA published Guidance on Dossier and Substance Evaluation (hereafter, ‘Guidance on Evaluation’).⁵⁵ Unlike many of the Agency’s other guidance documents, the Guidance on Evaluation has not been updated since its publication. The Guidance on Evaluation stands at 139 pages and is said to be, “primarily intended” for use by staff within ECHA and Member State competent authorities responsible for carrying out evaluation tasks.⁵⁶ The document is stated to, “also be useful” for registrants, downstream users and third parties, “to better understand” how evaluation will be performed and how decisions relating to evaluation will be taken.⁵⁷ Accompanying the Guidance on Evaluation is the August 2008 Guidance on Priority Setting for Evaluation (hereafter, the ‘Guidance on Priority Setting’).⁵⁸ This document is unusual in that it states that it, “is not intended to be used as stand alone guidance and takes into account other REACH guidance and processes, in particular the guidance on evaluation.”⁵⁹ The Guidance for Priority Setting is “primarily intended” to be used by staff within ECHA who are dealing with the priority setting of dossier evaluation, but “will also be useful” for registrants and Member State competent authorities.⁶⁰

The Guidance on Evaluation is technical and process oriented, containing a series of step-by-step flowcharts, tables of tasks and responsibilities, reporting formats and checklists to be used by Agency staff. In this regard, this guidance (produced by ECHA) mainly aims at channelling the actions of the Agency’s own staff. Even more prescriptive (as regards process) is the Procedure for Dossier Evaluation

⁵⁵ ECHA (n 7)

⁵⁶ *ibid*, 9

⁵⁷ ECHA (n 7) 10

⁵⁸ ECHA (n 8)

⁵⁹ *ibid*, 7

⁶⁰ *ibid*

published by ECHA in March 2011. This is not one of the Agency's guidance documents and is housed on that part of ECHA's website dedicated to Evaluation.⁶¹ The Procedure for Dossier Evaluation is very clearly aimed at ECHA staff and sets out the 26 separate steps that form part of dossier evaluation.⁶² It is noteworthy that such an important procedural guide is not one of ECHA's guidance documents and yet it actively sets out norms for how the Agency's staff should work. In the context of hard/soft law, the specificity of this procedure document would seem to suggest that it shapes and channels the day-to-day operation of REACH just as much as the official guidance documents and, arguably, just as much as the text of the Regulation itself. 'Guidance', as was demonstrated in Chapter 4, comes in a variety of forms under REACH. ECHA has 20 'Procedure' documents on its website, all housed in the 'The Way We Work' section and not in the 'Support' section (where the other guidance is housed).⁶³

Dossier Evaluation – Compliance Check

Dossier evaluation is split into two sub-categories: (i) a compliance check (not to be confused with the completeness check detailed above); and (ii) an examination of testing proposals. While the three evaluation tasks (compliance checks, testing proposal reviews and substance evaluation) are independent of each other in REACH, the Guidance on Evaluation suggests that, "certain links [between them] are evident, and results and information obtained in the different tasks should be used and linked in an intelligent manner."⁶⁴ This lack of clarity on overlaps is seen elsewhere in REACH (for example, in the following Chapter on Authorisation and Restriction).

The aim with the compliance check is for ECHA to examine the chosen registrations in order to verify that certain information is in compliance (in terms

⁶¹ See: <<http://echa.europa.eu/regulations/reach/evaluation/examination-of-testing-proposals>> accessed 10 August 2014

⁶² ECHA, 'Procedure for Dossier Evaluation' (PRO-0017.03, July 2013) – see: <http://echa.europa.eu/documents/10162/13607/procedure_dossier_evaluation_20110329_en.pdf> accessed 10 August 2014

⁶³ See: <<http://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures>> accessed 10 August 2014

⁶⁴ ECHA (n 7) 12

of content, format, quantity etc) with the requirements of the Regulation.⁶⁵ The Guidance on Evaluation details that, “The main purpose of a compliance check is to evaluate whether a registrant is meeting his obligations.”⁶⁶ For this process, the difference in language between the text of REACH and the Guidance on Evaluation is striking. Article 40(1) of REACH sets out the purpose of the compliance check simply in terms of compliance with rules found elsewhere in the Regulation. The Guidance on Evaluation, however, sets out that the purpose of a compliance check, “is to check the adequacy of the information submitted, which can be defined by its reliability and relevance.”⁶⁷ These criteria, reliability and relevance, are then defined in more depth in the Guidance on Evaluation. The reader will recall the use of these criteria in other ECHA guidance (see Chapter 5 on SIEFs and the Agency’s guidance on data sharing and information requirements). This, it is suggested, is something more than ECHA simply amplifying the text of REACH and that, in putting forward two new criteria, the Agency is effectively translating the requirements of the Regulation to something potentially more than is required.

When it comes to selecting dossiers for a compliance check, ECHA is entitled to rely on any information submitted by a third party on a substance which underwent pre-registration,⁶⁸ or on any information on substances submitted to them by competent authorities in the Member States.⁶⁹ Thus, it is possible for Member States and third parties to ‘suggest’ specific registration dossiers for compliance check evaluation. From inception of the compliance check, ECHA has twelve months within which to draft a decision requiring the registrant(s) to submit any information needed to bring the registration into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information.⁷⁰

⁶⁵ Article 41(1)

⁶⁶ ECHA (n 7) 11

⁶⁷ ECHA (n 7) 46

⁶⁸ Article 41(6)

⁶⁹ Article 41(6), Article 124

⁷⁰ Article 41(3)

Article 41(5) of REACH sets out that compliance checks are intended to take place for no fewer than 5% of all registration dossiers received for each tonnage band.⁷¹ Without wishing to state the overly obvious, this means that up to 95% of all registration dossiers sent to ECHA will never undergo any form of assessment (other than the completeness check box ticking exercise). Article 40(5) of REACH sets out that certain substances may be prioritised for a compliance check as part of dossier evaluation. The text of REACH is not exhaustive as to when a substance should be prioritised for a compliance check, but three possible criteria are given. The first is where information on classification and labeling or study summaries has been submitted separately to the registration dossier.⁷² The second is where a registration dossier is submitted without all of the information required by Annex VII.⁷³ The third is where a dossier is submitted for a substance listed in the Community Rolling Action Plan. This plan is discussed in more depth below in the section on Substance Evaluation. In its Guidance on Priority Setting on Evaluation, ECHA details that, “with the exception of random selection”, no other criteria (save those detailed in REACH and discussed above) should be used to prioritise registration dossiers for a compliance check.⁷⁴ The reason given for this approach is interesting. Here, the Agency comments that,

“Rationale for this recommendation is that random selection is considered the best means to render the selection of a registration dossier for compliance check unpredictable for a registrant and thus will help to ensure that the quality of the submitted dossiers increases over time.”⁷⁵

Given this, it may not make as much difference that only 5% of all dossiers are evaluated. The numbers to date of evaluations are discussed later on in this section. In terms of how prioritisation actually happens, it is worth stating that the Guidance on Priority Setting for Evaluation is very much a ‘how to’ guide for ECHA staff, in particular on how to search the REACH-IT systems according to the various prioritisation criteria. This is another example of the standardisation, or action channeling, function of the Agency’s guidance.

⁷¹ Although the Commission has the power to vary this percentage in accordance with Article 41(7)

⁷² Article 40(5)(a)

⁷³ Article 40(5)(b)

⁷⁴ ECHA (n 8) 30

⁷⁵ *ibid*

Dossier Evaluation – Testing Proposals

Where a substance is manufactured in quantities greater than 100 tonnes per year, the registration dossier for that substance will set out proposals for how certain missing data on the intrinsic properties of that substance will be generated. Under the second element of dossier evaluation, *all* testing proposals for these so-called “higher tier studies” need to be examined by ECHA.⁷⁶

REACH is silent on how the examination should be conducted or on the purposes of the examination. Article 40(1) simply states that, “The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance.” The Guidance on Evaluation is more expansive and sets out that “two main aspects” in relation to the examination of testing proposals can be identified.⁷⁷ The first is whether the testing proposal complies with standard testing requirements; the second is whether the reasons for proposing additional testing are appropriate.⁷⁸

Article 40(1) further sets out that,

“Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes per year with uses resulting in widespread and diffuse exposure.”

As detailed earlier in this section, ECHA has produced Guidance on Priority Setting for Evaluation. In the context of priority setting and the review of testing proposals, the language used in the guidance is striking. It details that,

“With regard to the criteria that should be used for priority setting, it was agreed that the prioritisation criteria mentioned in the legal text (i.e. Art. 40(1)) should in principle be given preference over further criteria proposed. Ideally, the legal criteria should be used for initial selection of the testing proposals that should be examined with priority

⁷⁶ Article 40(1)

⁷⁷ ECHA (n 7) 20

⁷⁸ *ibid*

and the supplementary criteria be used to further rank (i.e. order) the prioritised proposals.”⁷⁹

It is submitted that this statement in the guidance is an intentional mis-reading of Article 40(1). Elsewhere in REACH (for example, in the context of compliance check prioritisation, discussed above), the Agency is given a non-exhaustive list of substances or classes of substance that may be prioritised. This flexibility and discretion is not, however, seen in Article 40(1), which clearly states that “Priority shall be given...” As a result, there is not the room for ECHA, in this particular instance, to say that it will “give preference” to the Article 40(1) criteria over further criteria that may be proposed. This, it seems, is a translation of the clear wording of REACH into something quite different by the Agency.

The review by ECHA of the testing proposals may lead to one of five possible decisions, namely: (i) approval of the test proposal; (ii) approval of the test proposal as modified; (iii) a rejection of the test proposal; (iv) a rejection or approval of the test proposal combined with an obligation to do additional tests; or (v) where a number of registrants or downstream users have submitted the same proposal, approval of that proposal subject to agreement within 90 days of one actor performing the test on behalf of all who submitted.⁸⁰ For non phase-in substances, ECHA must prepare a draft decision within 180 days of receiving a registration or downstream user report containing a testing proposal.⁸¹ For phase-in substances, the deadlines for the draft decisions are staggered depending on when the testing proposals are received (so, for example, for a test proposal received by 1 June 2018, ECHA has until 1 June 2022 to prepare its draft decision.)⁸²

Substance Evaluation

Substance evaluation is the pro-active assessment of registration dossiers by Member States. In many ways, it resembles the compliance check undertaken by ECHA, discussed above. The main difference is that substance evaluation is meant

⁷⁹ ECHA (n 8) 12

⁸⁰ Article 40(3)

⁸¹ Article 43(1)

⁸² Article 43(2)

to be targeted to particular chemicals of concern as identified by ECHA and Member States and has the potential to lead to further regulatory action. However, there are overlaps between the two processes. Article 44(1) of REACH sets out that,

“In order to ensure a harmonised approach, the Agency shall in cooperation with the Member States develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach.”

These criteria (based on hazard information, exposure information and substance tonnage) lead into a three year Community rolling action plan (known as the ‘CoRAP’), detailing the substances to undergo substance evaluation each year and which Member State has responsibility for evaluating which substance.⁸³ The evaluating Member State has 12 months from the publication of the CoRAP to decide whether it needs to request further information from the registrants to clarify the concern. This request might go beyond the standard information requirements of REACH (Annexes VII to X) and may relate to the intrinsic properties of the substance or its exposure.⁸⁴ The first CoRAP was adopted by ECHA on 29 February 2012 and covers a period of three years (2012-2014). It is updated annually. The CoRAP is housed on ECHA’s website and includes: (a) the names of the substances to be evaluated; (b) an indication of the initial concern about the substances; (c) the names of the Member States responsible for the evaluation of each substance; and (d) the year of evaluation.⁸⁵ At present, 152 substances are on the CoRAP.⁸⁶

With substance evaluation, the role of ECHA is one of co-ordination, with the active assessment of the relevant substance undertaken by competent authorities in the Member States (or third parties appointed on their behalf.)⁸⁷ The Guidance on Evaluation is detailed on the steps to be taken as part of substance evaluation and

⁸³ Article 44(2). It is worth noting that a Member State can put itself forward as the competent authority for evaluating a particular substance in accordance with procedures detailed in Article 44(2) and (3).

⁸⁴ Article 46(1)

⁸⁵ See: <<http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan>> accessed 10 August 2014

⁸⁶ See: <<http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>> accessed 10 August 2014

⁸⁷ Article 45(1)

aims at harmonising approaches between Member State competent authorities. For example, it offers practical suggestions on ‘targeted’ substance evaluation, where foci are applied to specific parts of the registration dossier;⁸⁸ as well as setting out a detailed methodology for how to conduct substance evaluation.⁸⁹ While the language of the guidance is normative (and the use of ‘should’ abounds) the tone is not prescriptive and there is a sense of the Agency setting out what it considers best practice without actually telling MSCAs what to do. This best practice advice is a clear example of ECHA’s guidance having a standardisation function.

Article 48 sets out that, once substance evaluation has taken place, “the competent authority shall consider how to use the information obtained for the purposes of” either: (a) identifying a Substance of Very High Concern (see Chapter 7); (b) initiating the Restriction process under REACH (see Chapter 7); or (c) harmonising the classification and labeling of substances (which is outside the scope of this thesis). ECHA’s own website sees the purposes of substance evaluation as somewhat wider,

“The evaluation may in the end conclude that the risks are sufficiently under control with the measures already in place. Otherwise, it may lead to the proposal of EU-wide risk management measures such as restrictions, identification of substances of very high concern, harmonised classification or other actions outside the scope of REACH.”⁹⁰

This wider view of possible next steps is also seen in the Guidance on Evaluation, which sets out the potential for action under the Water Framework Directive and/or voluntary measures by registrants (in addition to those actions set out in REACH).⁹¹ This, it is suggested, is an example of ECHA translating the text of REACH into something which the Agency sees as more workable, and more effective, in day to day regulation of chemicals within the EU.

⁸⁸ ECHA (n 7) 67-72

⁸⁹ ECHA (n 7) 72-78

⁹⁰ See: <<http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation>> accessed 10 August 2014

⁹¹ ECHA (n 7) 87

Reports on Evaluation

In line with Article 54 of REACH, by 28 February of each year, ECHA has to publish a report on the progress it has made over the previous calendar year on its obligations in relation to Evaluation. ECHA is specifically required to include recommendations to potential registrants to foster improvement in the quality of future registrations in these reports. 6 reports have thus far been published.⁹² The story told in these reports, of the progress of REACH and the embedding of ECHA into the regulatory landscape of the EU, is worth exploring. A mere 98 registration dossiers were submitted to the Agency in 2008: of these, only 10 passed the completeness check and ECHA started a compliance check on 3.⁹³ The 2008 report is available only in English and consists of 6 sparse pages. By 2009, the Article 54 report looks more professional and, at 30 pages, is more expansive.⁹⁴ The report also details the increasing workload of ECHA. In 2009 ECHA received 406 complete registration dossiers and initiated evaluation of 35 dossiers, 27 compliance checks and 8 examinations of testing proposals. By 2012 (the most recent report), one registration deadline has passed and the Agency is operating at full speed, having conducted 295 compliance checks, examined testing proposals from 557 dossiers and facilitated the acceptance of 36 substances Member States for substance evaluation.⁹⁵

⁹² See: <<http://echa.europa.eu/web/guest/regulations/reach/evaluation>> accessed 10 August 2014

⁹³ ECHA, 'Progress Report' (2008) – see: <http://echa.europa.eu/documents/10162/13628/progress_report_2008_en.pdf> accessed 10 August 2014

⁹⁴ ECHA, 'Progress Report' (2009) – see: <http://echa.europa.eu/documents/10162/13628/progress_report_2009_en.pdf> accessed 10 August 2014

⁹⁵ ECHA: 'Progress Report' (2012) – see: <http://echa.europa.eu/documents/10162/13628/evaluation_report_2012_en.pdf> accessed 10 August 2014

Information Provisions in Relation to Articles

The Consumer “Right To Know”

We turn now to rights granted to non-business third parties under REACH to be sent (or to be provided with on demand) various classes of REACH related information. Labelled an “important responsibility”,⁹⁶ Article 33(2) grants to consumers a limited ‘right to know’ about the products they buy and the substances contained therein. The text of this provision is worth replicating in full:

“On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) [i.e. substances on the Candidate List] in a concentration above 0.1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.”

The relevant information has to be provided, free of charge, within 45 days of the request. The term “consumer” is not defined in REACH, but a “supplier of the article” means “any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market”.⁹⁷ The definition of what constitutes an “article” is equally broad.⁹⁸ Note here that the sole requirement for Article 33(2) to activate is the concentration threshold of the Candidate List substance in the article. There is not, as is elsewhere common in REACH (for example, see below in relation to Article 7(2) notification obligations), a tonnage trigger as well, in which suppliers would only have an obligation where the concentration level in a given product was met *and* the sum total of that substance in all products supplied over the course of a year exceeded a certain volume threshold. Given this, the importer of a single article into the EU which contained a Candidate List substance in the relevant concentration would be captured by Article 33(2) (and Article 33(1) (below) as well).

⁹⁶ Recital 56

⁹⁷ Article 3(33)

⁹⁸ Under Article 3(3) “article” means “an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”. This could be anything from the keyboard used to type up this text to the empty paper coffee cup sat in front of the author.

In Chapter 3, an hypothetical scenario concerning the (fictitious) chemical *legalene* was introduced, where *legalene* is a highly catalytic substance used in the production of inks for the printing of law textbooks. Let us now say that *legalene* has been found to be a SVHC and has been placed on the Candidate List (a process explored in depth in Chapter 7). As is set out in Chapter 3, under REACH the primary regulatory obligations for *legalene* rest with its manufacturers. However, under Article 33(2) and the consumer ‘right to know’, the printing company that prints the textbook, the wholesaler who then buys the textbooks and the small, independent bookstore that sells the textbooks on to students would potentially each be required to provide certain information to consumers where a request for that information had been put to them.⁹⁹ This, at first glance, seems somewhat odd. Let us take the small bookstore that sells to students the textbooks that contain *legalene*. They may well have never heard of REACH,¹⁰⁰ or if they have, they may have limited resources with which to understand and/or manage their REACH obligations. One might question what meaningful purpose is served in allowing the student owner of the textbook to ask the bookstore for information on *legalene* in this situation? Under Regulations 11 and 12 of The REACH Enforcement Regulations 2008, discussed in more depth in Chapter 8, breach of the Article 33(2) obligation could lead (in the worst case) to an unlimited fine or imprisonment for up to two years (or both).

ECHA has produced Guidance on Requirements for Substances in Articles, which relates to obligations under Article 7,¹⁰¹ and Article 33 of REACH.¹⁰² This guidance is detailed as regards what is (and is not) an article and when (and when not) substances are intended to be released from articles. However, less than 2 of

⁹⁹ There has been some debate on the exact breadth of those who have obligations under Article 33(2) (see, for example, the March 2007 Position Paper by the Free Trade Association “The REACH Information Duty” – see: <<http://www.fta-eu.org/doc/unp/opinion/en/FTAREACHInformationDuty.pdf>> accessed 10 August 2014). Part of this goes to the understanding of the phrase “placing an article on the market” and whether or not a broad interpretation of this phrase is appropriate. The issue lies in the definition of “placing on the market” in Article 3(12) of REACH in a manner which, on its face, seems inconsistent with other definitions elsewhere in EU law. Given this matter has yet to be decided by the European Union courts (or, indeed, any national courts), the broad interpretation is the one which underpins the remainder of the commentary on this section.

¹⁰⁰ Although Recital 8 of REACH specifically addresses the need to take account of the impact of the Regulation on small and medium enterprises, this is not seen in the main body of REACH and Article 33 has the potential to hit SMEs particularly hard.

¹⁰¹ Namely, the registration or notification of certain articles. ECHA (n 2)

¹⁰² ECHA (n 4)

the 87 pages of the Guidance are devoted to the communication obligations in Article 33.¹⁰³ There is no attempt made at standardisation in this particular area nor any discussion of what form good practice risk communication with the public might take. This is striking. The Guidance simply notes that there are variety of formats which could be used to communicate data and that the relevant supplier etc, “must choose a format that will ensure that the information is readily available to the recipient of the article or the consumer, always taking into account the particular situation of use.”¹⁰⁴ While not relevant to this specific issue, it is worth noting that this Guidance document did not find full support from all Member States and is published with a covering caveat. This details the lack of full support and warns that, “Consequently, companies may face diverging enforcement practices as to some of its aspects.” This is striking for two reasons. The first, and most obvious, is that of divergence in enforcement: while REACH is a Regulation and directly applicable, enforcement is a matter for individual Member States. As will be seen in Chapter 8, this has caused a number of issues. The second is that the warning implies that, where guidance *does* have the full support of Member States, it will be treated as authoritative by Member State authorities with competence for REACH enforcement and by ECHA and the Commission. As such, ECHA’s post legislative guidance helps to shape the enforcement of the Regulation across the EU. The lack of consensus with this guidance document is discussed in further depth in Chapter 9.

For the purposes of the following discussion, let us call articles to which Article 33 applies “Applicable Articles”. Guidance from ECHA details that the Article 33 obligations apply to articles supplied *after* the publication of the Candidate List.¹⁰⁵ Let us assume that *legale* went onto the Candidate List on 1 September 2012. Students who bought textbooks on 31 August 2012 have no Article 33(2) rights. However, their friends, who bought the same textbook from the same supplier, but one day later on 1 September 2012, would have had such rights. This distinction seems somewhat arbitrary. On a practical level, the ability of a supplier to provide information to consumers relating to Applicable Articles requires them to know:

¹⁰³ *ibid*, 18-19

¹⁰⁴ ECHA (n 4) 19

¹⁰⁵ ECHA (n 4) para 2.3

(a) which substances are present in their articles; and (b) in what concentrations those substances are present. This may be no easy thing, especially for products with cross border supply chains and in which the ultimate supplier may have no power whatsoever to compel disclosure by an entity far down the supply chain of the chemicals they are using.¹⁰⁶

As set out above, the text of REACH is such that discharge of the Article 33(2) obligation can be achieved simply through the disclosure of the name of the SVHC on the Candidate List which is included in the article above the relevant concentration. Going back to our *legalene* example, the bookseller could respond to the student textbook owner simply by saying “The textbook which I supplied you does contain *legalene* in [X] concentration”. One might query what value this holds for the student? Given this, it would appear that Article 33(2), while seemingly laudable in aim and outlook, suffers from impracticality of discharge and limited real world worth. This supposition is borne out by a number of empirical enquiries into the operation of Article 33. One study found that some companies provide the consumer with a reply in a different language from that of the request.¹⁰⁷ Others responses from suppliers provide only very general information about safety bearing little relation to the consumer’s query.¹⁰⁸ At the other end of the spectrum, some companies have provided consumers with a 30-page technical Safety Data Sheet (designed for industry stakeholders for occupational health and safety purposes).¹⁰⁹ Given this divergence of practice, this is an area in which ECHA guidance might usefully have been produced.

¹⁰⁶ While in practice as a solicitor in the City of London, this was a common issue encountered by the author on behalf of his clients. At times, a supplier keen to comply as fully as possible with REACH was simply not able to be certain of all the chemicals used in their products due to recalcitrant entities further down the supply chain. This then left the supplier needing to undertake so-called ‘destructive testing’ in an attempt to understand the chemical composition of their products and the relevant (and all important) concentration levels of those substances.

¹⁰⁷ BEUC, ‘Chemicals, Companies and Consumers: How Much Are We Told?’ (Report by the European Consumers Organisation, 2011) 11

¹⁰⁸ Crioc, ‘REACH – The Right to be Informed of the Presence of Dangerous Chemical Substances in Products’ (Report by the Belgian Centre for Research and Information for Consumer Organisations, 2012) 7 - see: <<http://www.oivo-crioc.org/files/fr/6587fr.pdf>> accessed 10 August 2014

¹⁰⁹ EEB, ‘The Fight to Know’ (European Environmental Bureau 2010) 15 – see: <<http://www.eeb.org/EEB/?LinkServID=8BBC1DF8-C9C7-8B93-CA5F42033F11A3AD>> accessed 10 August 2014

The “Industrial Customer” Right to Know

Article 33(1) is a form of mirror to Article 33(2), but applies to non-consumers (“recipients of articles”)¹¹⁰ and is a positive, pro-active obligation to provide information on the “safe use” of Applicable Articles (rather than the reactive Article 33(2) which requires the trigger of a request for information from the consumer). Like Article 33(2), there is little specificity in Article 33(1) on the breadth or depth of information required to be transmitted (other than the fact that the information needs to allow the “safe use” of the Applicable Article and, as a minimum, needs to include the name of the substance).

Article 33(1) is also silent as to the method of delivery of the “safe use” information to recipients of Applicable Articles. Here, such information could be transmitted via the article’s packaging; it could be sent via email or hard copy correspondence; it could be detailed on a specific website etc. Given that the aim of the provision is to ensure the “safe use” of the article, the lack of uniformity on delivery may water down its impact. As noted above, the Guidance produced by ECHA on substances in articles lacks specificity in this area. It is also worth noting here that existing product safety legislation within the EU (such as the General Product Safety Directive)¹¹¹ already requires safe use information to be contained on a product’s packaging or in user manuals or as part of the product description (and so there may be a degree of overlap). REACH’s sister Regulation (i.e. the CLP Regulation)¹¹² deals with the packaging of chemicals (and not the products into which they are ultimately incorporated). However, as noted in Chapter 1, CLP is wholly without the scope of this thesis.

Supplier Notification Obligations

¹¹⁰ Article 3(35) defines a recipient of an article as “an industrial or professional user, or a distributor, being supplied with an article but does not include consumers”

¹¹¹ Council Directive (EC) 2001/95 on general product safety [2001] OJ L 011

¹¹² Council Regulation (EC) 1272/2008 on classification, labeling and packaging of substances and mixtures [2008] OJ L 353

In addition to the ‘right to know’ provisions detailed above, there are also notification obligations on suppliers to notify ECHA, under Article 7(2), if certain conditions are met regarding the content of Candidate List substances in articles they supply. Notification is required when: (a) the substance is present in those articles in quantities totaling over one tonne per producer or importer per year; and (b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w). In addition, registration is only required where the substance has not yet been registered for that specific use.¹¹³ The Guidance on Substances in Articles produced by ECHA makes it clear that the threshold concentration above applies to articles as produced or imported and “does not relate to the homogeneous materials or parts of an article, as it may in some other legislation”.¹¹⁴ ECHA gives the following example in their Guidance:

“If imported buttons for jackets contain such substance in concentrations of 0.5% (w/w), this needs to be communicated to the recipient. If these buttons are imported as part of jackets the concentration of the substance in relation to the imported article (the jacket) will probably be lower than 0.1% (w/w) and in that case no information would have to be communicated.”¹¹⁵

In this instance, the Guidance produced by ECHA reduces the burdens on industry. This is an example of the Agency translating the text of the Regulation (in this instance for the benefit of registrants). The contents of the notification are set out in Article 7(4). There is an exemption for notification where the supplier can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal.¹¹⁶ In such cases, the producer or importer are obliged to supply “appropriate instructions” to the recipient of the article. Notification is only required as from 1 June 2011 and, thereafter, no later than 6 months after the substance has been included on the Candidate List.¹¹⁷ This then places an obligation, if not legal then practical, on suppliers to: (a) know every substance in their articles (and in what concentrations);¹¹⁸ and (b) regularly monitor the Candidate List and cross check against the substance lists they have

¹¹³ Article 7(6)

¹¹⁴ ECHA (n 4) para 2.2

¹¹⁵ ECHA (n 4) para 2.3

¹¹⁶ Article 7(3)

¹¹⁷ Article 7(7)

¹¹⁸ This data would also be needed for a supplier to comply with Article 33.

created (in case a notification is required at some point). While there is no obligation to notify if the use has already been registered, would/how would suppliers know this if they were not themselves engaged in the process of Registration? Especially if they are low down a supply chain? On a practical level, this is a somewhat odd provision.

Third Party Obligations

Supply Chain Obligations – Risk Communication

We turn now to information requirements imposed on non-registrants and non-suppliers. Article 34 details that “any actor” in the supply chain of a substance or a preparation is required to communicate the following information to the next actor or distributor up the supply chain:

- (a) new information on hazardous properties, regardless of the uses concerned; and
- (b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him.

Distributors are then to pass on that information to the next actor or distributor up the supply chain, creating (in theory) an upwards flow of information flow. This provision is extremely wide in ambit and it is questionable how effective it will be as a matter of practice (much like Articles 32 and 33 noted above). There is no ECHA guidance on the operation or application of Article 34.

Downstream User Notification Obligation

Though not a positive obligation, Article 28(5) empowers downstream users of chemicals to notify ECHA if a chemical which they use does not appear on the

List of Pre-Registered Substances¹¹⁹. The underlying rationale for this provision is that notification by the downstream user (which appears on ECHA's website) may prompt or remind those manufacturers or importers who should have pre-registered (but failed to do so) of their obligations under REACH. However, as of 10 August 2014, no DU had notified ECHA under this provision.¹²⁰ While ECHA has produced Guidance for Downstream Users, there is no reference to Article 28(5).

Reports (by ECHA, Commission, Member States)

As well as obligations on the private sector, REACH also contains provisions (common in EU law) on data generation and transmission by relevant regulatory agencies.¹²¹ Article 54 details that by 28 February of each year, ECHA is obliged to publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to Evaluation. This report must include, in particular, recommendations to potential registrants in order to improve the quality of future registrations. ECHA has published reports on its website for 2007 through 2012.¹²²

Article 117 details other reports required in respect of REACH. By 1 June 2010, the Member States are obliged to report to the Commission on the operation of the Regulation within their respective lands. By 1 June 2011, ECHA is obliged to report to the Commission: (a) on the operation of REACH; and (b) on the use of non-animal test methods and strategies used to generate the information required under the Regulation. Finally, by 1 June 2012, the Commission itself was then to report on the operation of REACH. The findings of the Commission's 2012 report have been noted where appropriate throughout this thesis.

¹¹⁹ The reader will recall that the mechanics of pre-registration, and the ensuing List of Pre-Registered Substance, are set out in Chapter 3.

¹²⁰ See: <<http://echa.europa.eu/en/information-on-chemicals/pre-registered-substances/substances-of-interest>> accessed 10 August 2014

¹²¹ See: Deirdre Curtin, 'Holding (Quasi-)Autonomous EU Administrative Actors to Public Account', (2007) 13(4) European Law Journal 523

¹²² See: <<http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports>> accessed 10 August 2014

Conclusions

This Chapter has outlined the main provisions in REACH which relate to information transmission, communication and dissemination. The Regulation also extends to data retention, with Article 36(1) obliging each manufacturer, importer, downstream user and distributor to “keep available” all the information they require to carry out their duties under this Regulation for a period of at least 10 years after they last manufactured, imported, supplied or used the substance or preparation.

What we see with REACH and information as a regulatory tool is a series of complex data flows (upwards, outwards and downwards) between and among the private and public sectors. While the Regulation is based on the principle that information on the intrinsic qualities of chemicals is a good in and of itself, the provisions in REACH that relate to information transmission, communication and dissemination are not always ideal, sufficiently well thought out on a practical level and/or able to meet their stated aims.

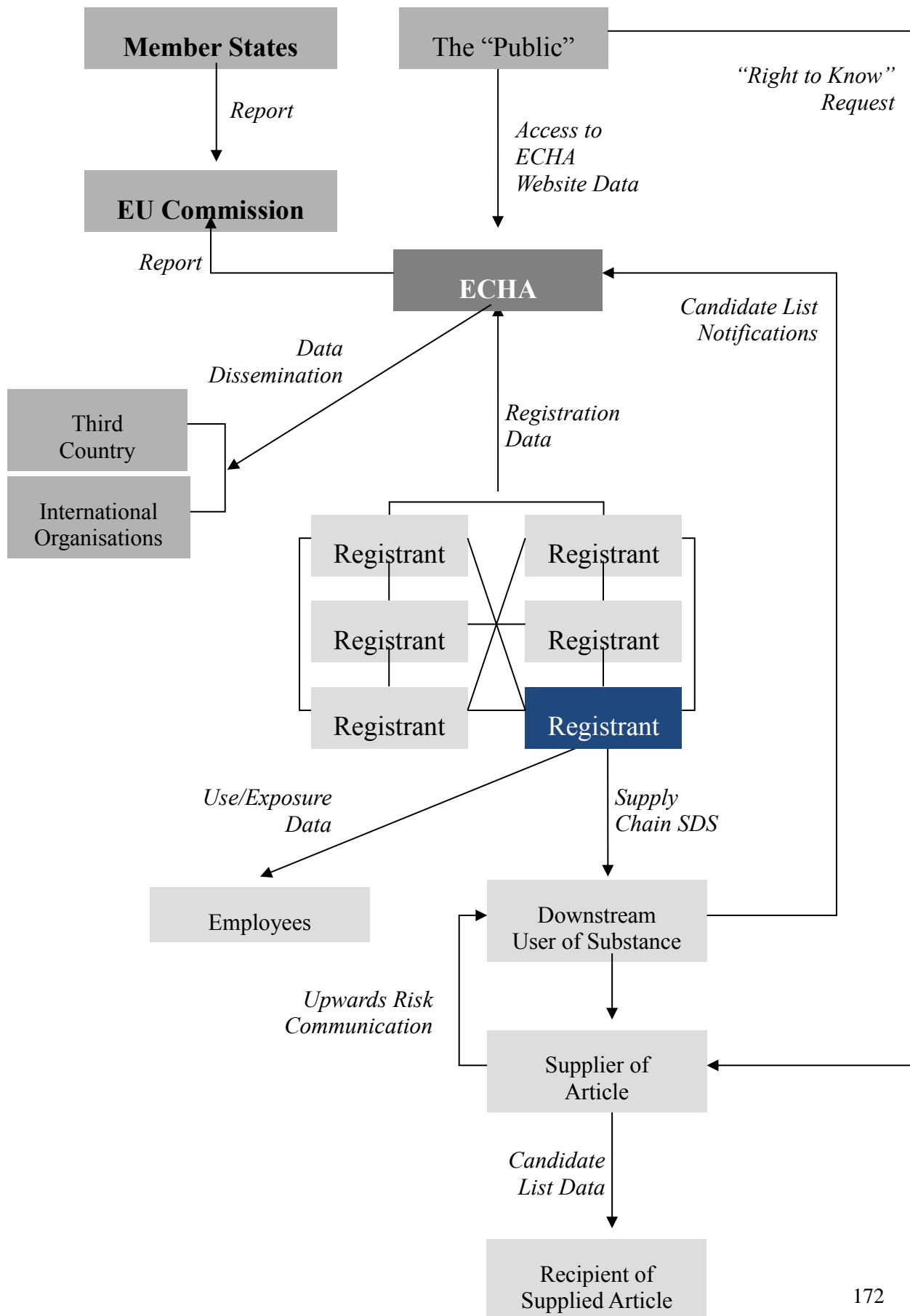
The guidance produced by ECHA in this area has highlighted examples of amplification, standardisation and the translation of the text of REACH. In the context of standardisation, the mammoth Guidance on Information Requirements and Chemical Safety Assessment is the most dense and most technical of all that published by ECHA. It is in fact 28 separate guidance documents, amounting to more than 200,000 words of text across 2,232 pages.¹²³ This Guidance aims to channel registrants down set paths as regards the compilation of the registration dossier to be sent to ECHA. The same is also true of the advice in the Guidance on the Compilation of Safety Data Sheets. One interesting point to arise from the review in this Chapter is that the Agency seeks to channel not only registrants in its guidance, but also ECHA staff and Member State competent authorities (as seen in the Guidance on Evaluation, which is primarily aimed at harmonizing Member State practices, and in the ‘how to’ Guidance on Priority Setting for Evaluation that effectively amounts to an ECHA staff manual).

¹²³ ECHA (n 5)

In the Guidance on the Communication of Information on the Risks and Safe Uses of Chemicals, however, ECHA goes some way to avoid telling Member States what to do in the context of risk communication. Here, the guidance provides an amplification and not a standardisation function, in that the Agency is offering up ‘pure’ advice without attempting to channel Member States down any particular course of action. This Chapter has also highlighted three specific instances of the ECHA translating the clear text of REACH for their own purposes: in the seemingly intentional misreading of Article 40(1) (over what criteria can, and can not, be used to set priorities for examining testing proposals); in setting out the permissible next regulatory steps following substance evaluation; and in the guidance on relevant threshold concentrations of SVHCs in articles for notification. The latter is a novel situation in which the Agency has translated the text of REACH as requiring something less of registrants than would seem to be required by the wording of the legislation.

More generally, it is worth noting that while the guidance produced by ECHA on information is thick with detail when it comes to business-to-business communication or technical matters, there is little that speaks to risk communication by registrants and suppliers with employees or the general public. In the following Chapter, how substances are banned, in full or in part, under REACH is reviewed.

DIAGRAM 6.1



CHAPTER 7

SUBSTANCE BANS UNDER REACH

Let us return to the application of REACH to the (hypothetical) chemical *legalene* (introduced in Chapter 3 and further discussed in Chapter 5). The members of the SIEF for *legalene* are undergoing the Registration process of REACH (see Chapter 6). As a result of their data gathering, generation and analysis, it becomes apparent (for the first time) that *legalene* is carcinogenic. The *legalene* SIEF files the registration dossier for *legalene* with ECHA, including the research reports detailing that the substance is carcinogenic, before the relevant registration deadline. The same REACH Registration process is also underway for the (hypothetical) chemical *jurisite* (introduced in Chapter 5). It becomes apparent that this chemical is toxic to the reproductive system. The *jurisite* SIEF file their registration dossier, with data detailing that *jurisite* is toxic, with ECHA. Due to recent reported fertility problems among the EU judiciary, and the widespread use of *jurisite* to powder judges' wigs, officials at Norway's environmental regulator had put *jurisite* on an informal watch list of substances they thought could be of concern. As a result, they ask ECHA to actively target *jurisite* and to review the *jurisite* registration dossier under the REACH Evaluation process (see Chapter 6). When ECHA look at the *jurisite* dossier filed by the *jurisite* SIEF, they see the data on toxicity, decide the substance could be a 'substance of very high concern' and begin to employ the REACH Authorisation process to ban any use of *jurisite* on the EU market. While ECHA is reviewing the *jurisite* dossier, France puts forward a proposal to engage the REACH Restriction process for the substance, arguing that urgent Community wide action in the form of an immediate ban is needed to protect the EU judiciary.¹ The operation of these processes, Authorisation and Restriction, which allow for limitations on the use and placing on the market of chemical substances under REACH, forms the heart of this Chapter.

¹ This hypothetical example somewhat mirrors what has happened to date in the context of the risk management of certain phthalates under REACH. This issue is discussed in more depth in the body of this Chapter.

While the *jurisite* dossier is actively reviewed, the dossier on *legalene* is never reviewed by ECHA, or by anyone other than the members of the *legalene* SIEF. As detailed in Chapter 6, only 5% of all registration dossiers are checked by ECHA and those substances subject to Evaluation under REACH are likely to be the 'known offenders' (that is, substances which regulators have reason to suspect are harmful, but for which they lack full chemical assays). There is no obligation, under REACH, on a SIEF to notify ECHA (or anyone else) if the data that registrants gather as part of the registration process suggests the relevant chemical is harmful. As a result, *legalene*, having been registered in accordance with REACH, is free to be manufactured, placed on the market or otherwise used in the EU despite it being carcinogenic.²

On first blush, this seems nonsensical. It is conceptually difficult to reconcile Registration under REACH with Authorisation and Restriction in the context of chemical risk management given the lack of correlation between data generation and analysis (Registration) and the pro-active regulation of harmful substances (Authorisation and Evaluation). Had one been asked to design a regulatory regime for chemicals from scratch, one might have thought that private sector information generation on chemicals, which flowed automatically into regulator-led chemical risk management would be a productive starting point. This is simply not the case under REACH. As the above *legalene* example illustrates, there is no obligation under REACH on private sector registrants to notify ECHA (or anyone else) if they determine that a chemical is harmful as part of registration. What this means then is that, on a date years to come, there could be harmful chemicals on the EU market which have been processed through the Registration elements of REACH but which were never caught by Evaluation, Authorisation or Restriction. This is somewhat worrying.

² In the real world, whether or not there is a regulatory obligation to notify a regulator, a company which becomes aware that a chemical is carcinogenic would have a difficult time avoiding future liability (post the point at which this knowledge accrued to them) for that substance (especially when the REACH registration dossiers are publicly available). However, the lack of positive reporting/notification obligation on the registrant/SIEF is striking.

As discussed above, REACH restricts the placing on the market or use of harmful substances through two processes: Authorisation and Restriction. The operation of these processes forms the heart of this Chapter. Though similar in regulatory outcome (the limiting of the use of harmful substances), and while both may be initiated by a Member State or the Commission via the preparation of a dossier of information, the scope, operation and consequences of the two processes are very different.³ While both are 'thin' in detail under REACH, each process is underpinned by detailed regulatory advice. ECHA has produced five guidance documents which directly relate to Authorisation and Restriction: (a) Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern;⁴ (b) Guidance for the preparation of an Annex XV dossier for Restrictions;⁵ (c) Guidance on the preparation of an application for Authorisation;⁶ (d) Guidance on the preparation of socio-economic analysis as part of an application for Authorisation;⁷ and (e) Guidance on Socio-Economic Analysis – Restrictions.⁸ Of these, three are principally aimed at Member States and the Commission,⁹ and two at industry/registrants.¹⁰ These five documents amount to 800 pages or over 305,000 words of guidance from ECHA. They are dense and technical pieces of advice. It is worth noting here that there was formerly a sixth guidance document produced by ECHA in 2008, which detailed how chemicals became 'substances of very high concern' (a trigger for regulatory action, discussed below). This document was, however, withdrawn by ECHA and

³ ECHA, 'Workshop on the Candidate List and Authorisation as Risk Management Instruments' (Workshop Proceedings, Helsinki, 21-22 January 2009) 28

⁴ ECHA, 'Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern' (Version 1, June 2007). See:

<http://echa.europa.eu/documents/10162/13638/svhc_en.pdf> accessed 10 August 2014

⁵ ECHA, 'Guidance for the preparation of an Annex XV dossier for restrictions' (Version 1, June 2007). See: <http://echa.europa.eu/documents/10162/13641/restriction_en.pdf> accessed 10 August 2014

⁶ ECHA, 'Guidance on the preparation of an application for authorisation' (Version 1, January 2011). See: <http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf> accessed 10 August 2014

⁷ ECHA, 'Guidance on the preparation of socio-economic analysis as part of an application for authorisation' (Version 1, January 2011). See: <http://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf> accessed 10 August 2014

⁸ ECHA, 'Guidance on Socio-Economic Analysis – Restrictions' (Version 1, May 2008). See: <http://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf> accessed 10 August 2014

⁹ (a), (b) and (e)

¹⁰ (c) and (d)

replaced with two 'General Approach' documents.¹¹ This withdrawal, and its consequences, are discussed later on in this Chapter.

Despite this voluminous guidance, what is not at all clear is whether or how Authorisation and Restriction are meant to operate vis-à-vis each other. ECHA itself admits that, “whereas Authorisation and Restriction are the main processes under REACH to limit the use (and risks) from chemicals, the choice for either of the two is not always obvious but very important as it can have major consequences.”¹² This is important because, as the Commission notes, “the decision to start one of the processes may limit the use of the other process for the same substance in the future.”¹³ The tensions between these two processes are further discussed later on in this Chapter. We begin by looking Authorisation and the concept of a 'substance of very high concern'.

Authorisation

Authorisation is somewhat a misleading name, implying abstract regulatory approval. Given the purpose and ambit of the relevant provisions, the process of Authorisation under REACH would perhaps have been better, although more verbosely, named 'substance bans with limited opportunity for consent of certain specified uses for certain specified short periods of time.' Authorisation seeks to identify the most harmful chemicals on the EU market in order to ban them, either in full or in particular circumstances, with the possibility of private sector applications for authorised uses of the substances so banned. Article 55 of REACH details that the (ambitious) aim of Authorisation is,

“... to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.”

This concept of substitution (the replacement of harmful substances with safer

¹¹ See: <<http://echa.europa.eu/guidance-documents/guidance-on-reach>> accessed 10 August 2014

¹² ECHA, 'Workshop on the Candidate List and Authorisation as Risk Management Instruments' (Workshop Proceedings, Helsinki, 21-22 January 2009) 6

¹³ *ibid*, 28

alternatives) is a key part of REACH, having been hard fought for during the negotiation of the Regulation.¹⁴ It is discussed in more depth later on in this Chapter.

The text of REACH sets out that there are several steps involved in the Authorisation process: the first is the identification of a “substance of very high concern” (“SVHC”); the second the creation of a Candidate List of SVHCs and prioritisation of substances from that list for regulatory action; and the third sees certain substances taken from the Candidate List and included in Annex XIV (the list of substances which may not be used in the Community save with specific authorisation). Once a substance is on the Annex XIV list, applications may be made for authorisation (that is, for specific uses of the substance to be permitted for a specific amount of time). Thereafter, authorisations will be granted or refused by the Commission. REACH sets out that certain substances are exempt from the Authorisation provisions. In addition, there are a number of situations in which, as provided by REACH, Annex XIV does not apply. These exemptions and exclusions, together with the various steps of the Authorisation process, are discussed in greater detail below.

It is worth noting here that, under REACH, Authorisation is not linked to Registration. It is, therefore, not a pre-requisite that a substance which is singled out for the Authorisation process must have first been registered. Indeed, there is no tonnage limit trigger for Authorisation (as there is for Registration). What this means then is that any substance on the EU market, whether or not it is caught within REACH’s Registration requirements, may be banned or have its uses limited. This has been of particular interest in the context of nanosubstances (where low production volumes mean there is likely to be little regulatory action under REACH via registration obligations).¹⁵

¹⁴ See Chapter 4 for a review of the history of REACH and associated literature.

¹⁵ For an overview, see: Robert G Lee and Steven Vaughan, ‘REACHing Down: Nanomaterials and Chemical Safety in the EU’ (2010) 2(2) *Journal of Law, Innovation and Technology* 193

SVHCs

As detailed above, the first step in the Authorisation process is the identification of a SVHC. Article 57 lays down broad guidelines for the substances which may be considered as SVHCs. These guidelines include the following three categories of substance:

“Those meeting the criteria for classification as carcinogenic category 1A or 1B, mutagenic 1A or 1B, or toxic for reproduction category 1A or 1B in accordance with Annex I to the CLP Regulation;¹⁶ or

Substances which are persistent, bioaccumulative and toxic (or very persistent and very bioaccumulative) in accordance with the criteria set out in Annex XIII of REACH; or

Substances (such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties) which do not fulfill the criteria of the first two broad categories, but for which there is, “scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern.”¹⁷ Such “other” substances will be identified on a case-by-case basis in accordance with a procedure set out in Article 59.”

What should be apparent from the above is that not every harmful substance will be capable of classification as a SVHC. This is for two reasons: the first is that the categories of SVHC are somewhat fixed and limited by Article 57 (there being no apparent regulatory appetite thus far to use the catch all “equivalent level of concern” limb of the provision); and the second is that REACH seeks only to regulate those harmful substances with the most serious effects.

On a practical level, the first step in the identification of a SVHC is the preparation of a dossier of information (the ‘Annex XV dossier’) by a Member State or by ECHA, the latter acting following a request from the Commission.¹⁸ In this dossier, the proposer needs to argue why a substance has properties of very high concern. Once the dossier is received by ECHA (or generated by the Agency itself) there is then a period of consultation, both with the public and with Member

¹⁶ Council Regulation (EC) 1272/2008 on classification, labeling and packaging of substances and mixtures [2008] OJ L 353

¹⁷ Article 57(f)

¹⁸ Article 59(2) and (3)

States.¹⁹ If no comments are made during the consultation process, ECHA will then include the SVHC on the Candidate List (on which, see the section below).²⁰ If there are comments, these are referred to the Member State Committee of ECHA for review (following which, the substance may be included on the Candidate List).²¹

The preparation of the Annex XV dossier for a SVHC is akin to the process in preparing a Registration dossier: namely, the collection of available data, the review and evaluation of that data, consideration of the need for new testing and, where appropriate, the execution of that new testing and its subsequent evaluation.²² This is set out in detail in ECHA's Guidance for the Preparation of an Annex XV Dossier on the Identification of Substances of Very High Concern (hereafter, the 'Annex XV Dossier Guidance'). Given that one of the reasons for REACH was the putting of the onus for chemical risk assessment onto the private sector from the State, it is interesting how the Authorisation (and Restriction) processes retain the pre-REACH status quo. It is also interesting to note that while consultation (of consumers, industry etc.) is required once a dossier has been finalised,²³ and there is then need for a decision on whether the substance goes onto become subject to Authorisation, Annex XV of REACH places no obligation on Member States (or ECHA, as appropriate) to consult during the preparation of the dossier (which would seem like a useful and practical step in data collection, if nothing else). However, the Annex XV Dossier Guidance sets out that,

“Although Annex XV includes no specific requirement for Authorities to engage in consultation, stakeholder involvement in the process is important. Consultation of industry and other stakeholders may be an important way for the Authority to obtain additional information although stakeholders have no legal obligation to provide information on the basis of informal consultation during the development of an Annex XV dossier.”²⁴

This is a good example of the Agency shaping behavior (in this instance, of itself and Member States) where the text of REACH is silent on something that seems to

¹⁹ Article 59(4)

²⁰ Article 59(6)

²¹ Article 59(7)-(9)

²² ECHA (n 4) 13ff

²³ Article 59(4)

²⁴ ECHA (n 4) 15

make common sense and is in the public interest. This is not an amplification of what is in the Regulation, but an additional (if softly phrased) requirement. As such, it is another example of the extrapolation function of ECHA's guidance.

Under the text of REACH and the Annex XV Dossier Guidance produced by ECHA, Member States and the Commission have complete discretion in the selection of potential SVHCs for which an Annex XV dossier will be produced. Importantly, REACH does not place any obligations whatsoever on Member States or the Commission to actively identify SVHCs and refer them to ECHA for consideration. As a consequence, any given Member State would be perfectly at liberty to never put forward an Annex XV dossier. Such inaction, while not impossible, would seem politically more difficult for the Commission.

In terms of where the information for an Annex XV dossier will come from, while it may appear, as drafted in REACH and discussed above, that the onus for preparing an Annex XV dossier rests with Member States (and occasionally ECHA), the guidance produced by the Agency suggests that such dossiers will build upon data sets generated by the private sector as a consequence of REACH:

“The normal procedure during the initial development of the Annex XV dossier would be that the readily available sources such as registration dossiers and results from previous evaluation(s) are obtained and reviewed.”²⁵

In many ways, this makes perfect sense. If a previous or current legal regime has already made a determination that a substance is of very high concern, there should be no need for a Member State to replicate this work. For example, the CLP Regulation lists the classification of certain substances. Here, for a substance which has been already classified and listed under that Regulation as a CMR, all a Member State may need to do is refer to such classification in the preparation of its Annex XV SVHC dossier.²⁶

However, in other instances, expecting Member States to rely on (or, indeed, wait for) substance data they have not themselves created may be problematic. For

²⁵ ECHA (n 4) 13

²⁶ Articles 59(2) and (3) of REACH states that SVHC dossiers, “...may be limited, if appropriate, to a reference to an entry in Annex VI of Regulation (EC) No 1272/2008 [the CLP Regulation].”

example, a substance may be exempt from Registration under REACH or the date for registration of a given substance may not be until 2018 (which would leave a Member State with years of inaction). It might also be the case that a substance of concern to a Member State is only produced in quantities lower than ten tonnes per year. Here, the registrant of that substance will not need to produce a Chemical Safety Report. However, CSR-like data (namely, relating to exposure and use risks) is needed for the Annex XV SVHC dossier (no matter what the production volume of the chemical concerned). ECHA's advice is also somewhat contrary in promoting the use of Registration dossiers for the purposes of SVHC identification when Authorisation is supposed to operate in respect of any substance, whether or not it has been registered and whether or not it is produced above the tonnage threshold at which Registration obligations kick in. Thus, for example, it is unlikely that many nanosubstances will be registered under REACH and, as a consequence, unlikely that Member States will target them for Authorisation (as the burden of producing all of the relevant data for the Annex XV dossier would be too great).

The other key problem with the Annex XV Dossier Guidance is that it assumes active review of Registration dossiers by Member State competent authorities. There is no evidence to suggest that this is, as a matter of fact, the case. Without wishing to belabour the point any further, the lack of any obligation on registrants to notify ECHA (or anyone else) that their registration dossier contains data suggesting the to-be registered substance is potentially a SVHC is a serious flaw.

As a final point in this area, the technical difficulty in having Member States and ECHA identify CMR substances and substances with PBT or vPvB properties may not be particularly great (whether they have the appetite to do so is another matter). However, as noted above, Article 57(f) also details that so-called "other" substances may be SVHCs where they give rise to an "equivalent level of concern". ECHA, in its guidance, does not specify criteria for when a substance will be of equivalent concern and acknowledges that "...science in this area is constantly developing."²⁷ At the same time, in the first official report on the

²⁷ ECHA (n 4) 23

operation of REACH, ECHA comment that while the identification of mono constituent substances as SVHCs is “fairly straight forward”, there is greater difficulty when it comes to multi-constituent substances or substances of unknown or variable composition or of biological origin (UVCBs).²⁸ These are two examples of where our materials science is lagging behind our regulatory ambitions (much like with REACH and nanomaterials). As a consequence, due to these issues in the practical identification of SVHCs and the preparation of Annex XV SVHC dossiers, the ability of the REACH authorisation process to lead to effective and robust chemical risk management may be (for the time being) limited.

The Annex XV Dossier Guidance, addressed to Member States, is 58 pages long. Created in June 2007, it is one of a small number of ECHA guidance documents produced in the early years of the Agency not to have been subsequently updated. Its specificity, density and length also stand in very much stark contrast to the very detailed, very technical and very long guidance given to registrants on the information required in their registration dossiers (see Chapters 5 and 67).

The Candidate List

Article 57 does not say that every SVHC will be included in Annex XIV (and thus banned save where specifically authorised), only that such substances “may” be so included. From the SVHCs for which ECHA has received (or generated) Annex XV dossiers, a number of these will be prioritised by ECHA and put onto a “Candidate List” (i.e. a list of substances which are potential candidates for banning and thereby subject to the REACH authorisation procedures).²⁹ There is a three month consultation window on all SVHC dossiers, after which ECHA prepares a recommendation for the Commission as to which of the substances should be prioritised for inclusion into Annex XIV. Recital 78 to REACH details that:

"The Agency should provide advice on the prioritisation of substances to be made subject to the authorisation procedure, to ensure that

²⁸ ECHA, ‘Report on the Operation of REACH and CLP, European Chemicals Agency’ (30 June 2011) 34

²⁹ Recital 77, Article 59(1)

decisions reflect the needs of society as well as scientific knowledge and developments".

This language (on Candidate List decisions reflecting the needs of society) is somewhat odd and vague and does not appear anywhere else in the text of the Regulation.

In its Annex XV Dossier Guidance, ECHA comments that prioritisation of SVHCs for regulatory control is important because:

“As the number of substances with identified properties of very high concern is expected to be relatively high, it is necessary to prioritise the progressive inclusion of identified substances into the system.”³⁰

This "high" volume of SVHCs put forward for consideration has not materialised. As of 10 August 2014, 155 substances have been put on the Candidate List,³¹ from 165 dossiers submitted by Member States and ECHA.³² Given that the Commission estimates that there are 3,000 SVHCs on the market and that REACH entered into force in June 2007, this is slow progress. Equally slow is the process of prioritisation of substances from the Candidate List for Authorisation. As of 6 February 2014 (the date of the last set of prioritisations), five sets of substances had been prioritised by ECHA for inclusion in the Authorisation List: the first set (of seven substances) in June 2009; the second (of eight substances) in December 2010; the third set (of 13 substances) in December 2011; the fourth set (of ten substances) in January 2013; and the fifth set (of five substances) in February 2014.³³ Article 56(3) details that ECHA should put forward substances to the Commission for consideration for inclusion in Annex XIV at least every two years.

Perhaps one of the reasons for the piecemeal and slow progress to date lies in the fact that there are no time periods set out in REACH (or ECHA guidance) as to when substances should be added to the Candidate List or recommended for

³⁰ ECHA (n 4) 9

³¹ See: <<http://echa.europa.eu/web/guest/candidate-list-table>> accessed 10 August 2014

³² See: <<http://echa.europa.eu/web/guest/registry-of-submitted-svhc-intentions>> accessed 10 August 2014

³³ See: <<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations>> accessed 10 August 2014

Annex XIV inclusion. Somewhat unsurprisingly, there has been much criticism of the pace at which substances have been added to the Candidate List. In its review of the operation of REACH, ECHA comments that this process, “is now [June 2011] proceeding relatively smoothly according to agreed procedures after a somewhat slow start.”³⁴ Despite this, the Chair of the Environment Committee of the European Parliament says that there are, “...around 500 substances that clearly meet the criteria of a substance of very high concern” and has berated the lack of slow progress by ECHA and Member States.³⁵ Early in 2010, the European Commissioners for DG Environment and DG Enterprise (Janez Potočnik and Antonio Tajani, respectively) secured the commitment from ECHA for a “roadmap” to put 136 SVHCs onto the Candidate List by 2012.³⁶ ECHA in turn wrote to Member States asking for their commitment to this target.³⁷

There are two points worth making here. The first is that the ‘roadmap’ target was ambitious and arbitrary. The second is that there have been very disparate efforts between Member States when it comes to preparing Annex XV dossiers on SVHCs. Table 7.1 below has been compiled from information on the ECHA website.³⁸ What is striking is: (a) the fact that only 12 of the 28 EU Member States have put forward dossiers for consideration; and (b) the difference in volume of dossiers produced by ECHA and Germany compared to the other proposers. As regards relative strength within the EU chemicals sector, Germany is the largest chemicals producer in Europe, followed by France, Netherlands and Italy.³⁹ In 2011, these four countries together generated 64.4% of EU chemicals sales, valued at €347.2 billion.⁴⁰ Such might explain then why Germany and France have

³⁴ ECHA (n 28) 32

³⁵ See the letter from Jo Leinen of 18 March 2010 to Antonio Tajani, Vice President of the European Commission and Commissioner for DG Industry. A copy of the letter can be accessed via: <<http://chemicalwatch.com/3500>> accessed 10 August 2014

³⁶ See the 25 March 2010 Press Release from the European Commission: <<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/360&format=HTML&aged=0&language=EN&guiLanguage=en>> accessed 10 August 2014

³⁷ See: <<http://chemicalwatch.com/3791>> accessed 10 August 2014

³⁸ See: <http://echa.europa.eu/consultations/authorisation/svhc/svhc_prev_cons_en.asp> accessed 17 September 2013. This webpage no longer (as of 10 February 2014) exists on the ECHA website.

³⁹ Cefic, ‘The European Chemical Industry in Worldwide Perspective’ (Facts and Figures 2012) 7 See: <<http://www.cefic.org/Documents/FactsAndFigures/2012/Facts-and-Figures-2012-The-Brochure.pdf>> accessed 10 August 2014

⁴⁰ *ibid*

submitted so many dossiers, but it does not explain the lack of dossiers put forward by Italy or the large number submitted by Austria, Sweden and Norway.

Table 7.1: Annex XV Dossiers

Proposer	Number of Dossiers Submitted
ECHA/Commission	54
Germany	38
France	17
Netherlands	14
Austria	10
Sweden	10
Norway	7
Belgium	3
Denmark	3
Slovakia	2
UK	2
Poland	1
Spain	1

While the SVHC 'roadmap' target was met, this was in large part down to the efforts of ECHA and not as a result of Member State activity. In its review of the operation of REACH, ECHA commented that, “MSCAs appear to suffer from a lack of resources for their [Candidate List] work and struggle with identification of suitable substances for further work.”⁴¹ Somewhat worryingly, the Agency also comments that, while (as set out above) in theory registration dossiers could be

⁴¹ ECHA (n 28) 32

used by ECHA or the MSCAs to provide the basis for the Annex XV dossiers, “the quality of information in these dossiers...is not necessarily sufficient to support the identification [of a SVHC]”⁴². Furthermore, “the data is not easy to screen in an automated manner.”⁴³ A second roadmap (known as the ‘2020 Roadmap’) is currently being debated, which would see ‘all known SVHCs’ on the Candidate List by 2020.⁴⁴ It does not appear as though a numerical target will be agreed. The draft 2020 Roadmap states that, “The Commission considers that no numerical goal should be identified in the Roadmap for the number of substances that will be included in the candidate list, as it cannot be pre-judged how many or which substances will be identified as relevant SVHCs.”⁴⁵ Exactly what this means is not entirely clear, but the draft does go on to give a ‘worst case estimation’ of an additional 440 substances being added to the Candidate List by 2020.⁴⁶ Arguably, these roadmaps are also soft law instruments and help to shape the day-to-day operation of one of the most important aspects of REACH (the removal of harmful substances from the market).

The Annex XIV Authorisation List

At the end of the SVHC prioritisation period (discussed above), there are three primary decisions to be taken by the Commission. These decisions were previously detailed in ECHA’s Guidance on the Inclusion of Substances in Annex XIV,⁴⁷ but (as noted earlier in this Chapter) this guidance document has been withdrawn.

Notwithstanding the removal of the guidance, the decisions to be taken by the Commission remain. The first is whether or not the prioritised SVHC will be subject to Authorisation under REACH. Here, different data is required at the different stages of the Authorisation process. For a chemical to go on the

⁴² ECHA (n 28) 33

⁴³ *ibid*

⁴⁴ Commission, ‘Roadmap on Substances of Very High Concern’ (COM 5867/13, 5 February 2013) See:

<http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf>
accessed 10 August 2014

⁴⁵ *ibid*, 5

⁴⁶ Commission (n 45) 12

⁴⁷ Copy on file with the author

Candidate List, what is relevant is data on the intrinsic properties of that chemical. For a chemical to go on the Authorisation List (i.e. for it to be banned), what is relevant is information on the uses of the chemical and what alternatives to that chemical exist.⁴⁸

The second of the three decisions to be taken, if the substance is to be subject to Authorisation, concerns which uses of the substance will not need authorisation (perhaps because other areas of EU law already regulate such uses). The third is the determination of the so-called “sunset date” (i.e. the final date on which the substance may be used for the particular uses without the need for authorisation). For the first seven substances recommended by ECHA for inclusion in Annex XIV, a sunset date of 18 months after “the relevant application date” (being the last date on which an application for authorisation could be received) was detailed for each.⁴⁹ In practice, what this means is that it could be up to four years after the date on which a substance is added to the Annex XIV Authorisation List that its use in the EU market will no longer be permitted.⁵⁰ This time lag is one of the key differences between the Authorisation and Restriction processes.

As set out above, five sets of substances (43 in total) have been prioritised by ECHA for inclusion in the Authorisation List. Of these, 22 have been put by the Commission onto the List.⁵¹ Whereas ECHA submitted the first list of SVHCs it thought suitable for inclusion in the Annex XIV Authorisation List to the Commission in June 2009, it was not until February 2011 that the Commission made a decision on inclusion.⁵² It has been reported that this delay was due to disagreement over guidance to be produced on applications for authorisation (and in particular the obligation to provide a substitution plan.)⁵³ Somewhat oddly, while REACH is prescriptive in other areas of the Authorisation process as regards

⁴⁸ Compare Articles 57 and 58

⁴⁹ Recital 9; ECHA, ‘Recommendation of the European Chemicals Agency of 1 June 2009 for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006’ (2009)

⁵⁰ ECHA (n 49) 4-5

⁵¹ See: <<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>> accessed 10 February 2014

⁵² See: <<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/196&format=HTML&aged=0&language=EN&guiLanguage=en>> accessed 10 February 2014

⁵³ See: <<http://chemicalwatch.com/3500>> accessed 10 August 2014

deadlines for regulatory action by EHCA and its various committees (on which, see below), there is no time frame given in the Regulation in which the Commission must (or should) take a decision following recommendations by ECHA on SVHCs suitable for authorisation.

Applying for Authorisation

Once a substance is included in the Authorisation List, there are two routes by which an application for authorisation can be made: the “adequate control route” and the “socio economic route”.⁵⁴ With the former, if an applicant can demonstrate adequate control of risks arising from the use of the substance on the Authorisation List, he may be granted an authorisation if: (a) there are no alternatives to that substance; or (b) there are alternatives and the applicant is going to provide a substitution plan for these (in which case the authorisation operates until the alternative substance can be put into use).⁵⁵ In this context, adequate control means that a threshold (i.e. a theoretically safe exposure level) can be established and the applicant is able to demonstrate, through exposure scenarios, that the relevant risks are below that threshold.⁵⁶

Where the “adequate control route” is not available (because adequate control cannot be demonstrated), an applicant will *only* be granted an authorisation via the “socio economic route”. Here, the applicant must demonstrate that: (a) there are no alternatives to the substance for which the authorisation is sought; and (b) the socio economic benefits of the use of substance (for the uses for which the authorisation is sought) outweigh the risks to human health and the environment.⁵⁷

Applications for authorisation are made to ECHA and may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the relevant substance.⁵⁸ Applications may be made by one or several persons.⁵⁹ REACH is somewhat limited on what is expected as regards the content of authorisation

⁵⁴ Article 60(2) and (4)

⁵⁵ Article 60(2)

⁵⁶ Annex I, para 6.4; and ECHA (n 7) 4

⁵⁷ Article 60(4)

⁵⁸ Article 62(1), REACH

⁵⁹ Article 62(2), REACH

application. Article 62(4) details that the application should include certain information, including the uses of the substance for which the application is sought, an analysis of alternatives and (where not submitted as part of registration) a chemical safety report for that substance. Article 62(4) amounts to a mere 184 words and, unlike elsewhere in REACH, there is no linked Annex to the Regulation specifying the application content in further detail. Instead, applicants wishing specifics on the authorisation application must look to guidance produced by ECHA. Published in January 2011, the ‘Guidance on the preparation of an application for Authorisation’ (hereafter, the ‘Application Guidance’),⁶⁰ is 125 pages long and amounts to some 61,706 words. What is particularly interesting in the Application Guidance is the discussion on alternatives. As noted at the start of this Chapter, one of the fundamental aims of the authorisation process is the substitution of SVHCs detailed on the Authorisation List with suitable alternatives. The Application Guidance details that, “An alternative is a possible replacement for the Annex XIV [Authorisation List] substance. It should be able to replace the function that the Annex IV substance performs.”⁶¹ The concept of “function” is not defined in the Application Guidance and may lead to future issues. Take a hypothetical example: the (fictional) substance *nanoweight* is a metal at the nanoscale used to make tennis rackets. It has been chosen because it is ten times lighter than its non-nanoscale (fictional) counterpart *racketite*, but provides equal strength and durability. However, *nanoweight* is found to be carcinogenic and a SVHC. Here, it could be easily argued that one should replace *nanoweight* with *racketite*, that the function of *nanoweight* is to give the tennis racket its shape and form and that *racketite* can perform an equivalent function just as well. It could also be argued that the benefits gained from using *nanoweight* (i.e. ten times lighter than *racketite*) are simply due to the properties of *nanoweight* and not to the function it serves. Article 60(5) sets out that, when assessing alternatives as part of the authorisation application, all “relevant aspects shall be taken into account by the Commission”, including whether the transfer to the alternative would result in “reduced overall risks to human health and the environment” and the “technical and economic feasibility of alternatives”.

⁶⁰ ECHA (n 6)

⁶¹ *ibid*, 41

Article 62(5)(a) of REACH details that the application for authorisation, “may include...a socio economic analysis conducted in accordance with Annex XVI”. This permissive (rather than obligative) language is somewhat odd, given that one of the authorisation application routes (detailed above) is that the socio economic benefits of the substance outweigh the relevant risks (for which it might be thought a SEA would be obligatory). Here, ECHA comment that, “In these cases [where applicants proceed with the “socio economic route” for authorisation], submission of an SEA [socio economic analysis] is, in practice, a compulsory part of an authorisation application. This is because presenting an SEA with the application is the only way for the applicant to demonstrate that socio-economic benefits outweigh the risks.”⁶² This, it is suggested, is an example of ECHA, in its guidance, translating the text of REACH to something which makes more real world sense than the Regulation as drafted. The language of the guidance in this respect makes important procedural demands not seen in the text of REACH. Some might argue that this is ECHA over stepping the limits of its authority. However, I would suggest that, in this instance, the particular drafting of Article 62(5)(a) of REACH is wholly at odds with the wider purpose of the Regulation and so ECHA’s ‘translation’ of the legislation in its guidance is acceptable.

If an applicant proceeds with the “adequate control route”, there is no obligation on him under REACH to provide a socio economic analysis (SEA). However, guidance from ECHA on SEA as part of authorisation applications (hereafter, the “SEA Authorisation Guidance”),⁶³ details that, “the [adequate control route] applicant is strongly advised to submit an SEA to support his [authorisation] application where he believes that socio-economic information is relevant.”⁶⁴ While not amounting to a full requirement for SEA (due to the “belief” qualification), this language does go further than the text of REACH in the practical obligations placed on “adequate control route” applicants. It is worth noting that the SEA Authorisation Guidance aims to “describe *good practice*” (emphasis as in original).⁶⁵ Describing this good practice takes up 238 pages and almost 100,000 words. What is not at all clear is the legal status of ‘good practice’

⁶² ECHA (n 7) 5

⁶³ ECHA (n 7)

⁶⁴ *ibid*, 4

⁶⁵ *ibid*

(particularly where, as here, the norms are so detailed and so prescriptive). This channeling of applicants to provide an SEA is more than amplification of the text of REACH and is another instance of ECHA effectively legislating to cover what may be perceived as gaps in the Regulation (i.e. another example of the extrapolation function)

Committee Opinions and Decision Making

Once an applicant has submitted an application for authorisation to ECHA, opinions on the application are given by ECHA's Committees for Risk Assessment ("the RAC") and Socio-economic Analysis ("the SEAC") within ten months of the application submission date.⁶⁶ Members of the RAC and the SEAC are appointed by ECHA's Management Board from candidates put forward by Member States and are to have expertise in the relevant areas. For the current RAC members, this appears to be expertise in toxicology and for the current SEAC members, expertise in economics and impact assessment.⁶⁷

The RAC is obliged to provide an assessment of the risks to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives.⁶⁸ The SEAC is obliged to provide an assessment of "the socio-economic factors,"⁶⁹ and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application.⁷⁰ These opinions, which must be prepared within ten months of

⁶⁶ Article 64(1)

⁶⁷ See: <http://echa.europa.eu/about/organisation/committees/seac_members_en.asp and http://echa.europa.eu/about/organisation/committees/riskassessment_en.asp> accessed 10 August 2014

⁶⁸ Article 64(4)(a)

⁶⁹ Nothing more is said on this in the text of REACH. These words are ambiguous. In addition, the guidance produced by ECHA on socio economic analysis in the context of authorisation is directed at applicants and does not direct the SEAC on the form and content of their opinion. See: ECHA (n 7)

⁷⁰ Article 64(4)(b)

receipt by ECHA of the authorisation application,⁷¹ are on forwarded by ECHA to the applicant, the Commission and the Member States⁷².

Whereas applications for authorisation are sent to ECHA and ECHA's committees provide opinions on those applications, the Commission is the body with the power to grant authorisations.⁷³ It is obliged to provide a draft decision on authorisation within three months of receipt of the RAC and SEAC opinions.⁷⁴ The final decision on whether or not to grant the authorisation is taken by the Commission via the 'advisory procedure' (in which the Commission is assisted by an advisory committee composed of representatives from the Member States.)⁷⁵ Any authorisation granted will be granted with conditions,⁷⁶ and will be subject to review after a set amount of time.⁷⁷ Importantly, Article 60(10) provides that, "Notwithstanding any conditions of an authorisation, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible."

As of 17 September 2013, only 1 application for authorisation had been received by ECHA.⁷⁸ By 8 July 2014 (the latest date on which statistics are available), this had grown to 13 applications.⁷⁹ There are a number of possible reasons for this. One might simply be a lack of time and that authorisation applications are currently being prepared by the relevant party/parties but have not yet been submitted. This reason seems credible given substances were only added to the Authorisation List for the first time in February 2011. However, another reason is that possible applicants have found alternatives to the SVHCs thus far identified and are, as a corollary, amending their production lines. A third is that the EU market for certain substances and products has contracted, as manufacturers and

⁷¹ Article 64(1)

⁷² Article 64(5)

⁷³ Article 60(1)

⁷⁴ Article 64(8)

⁷⁵ Articles 64(8) and 133(2); Council Decision (EC) 1999/468 laying down the procedures for the exercise of implementing powers conferred on the Commission [1999] OJ L 184

⁷⁶ Article 60(2)

⁷⁷ Article 60(8)

⁷⁸ See: <<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications>> accessed 10 August 2014

⁷⁹ *ibid*

importers abandon the practical application of identified SVHCs. Or, of course, it may be some combination of the three.

Exemptions from Authorisation

Once a substance is listed in Annex XIV and the ‘sunset date’ has passed, it cannot be used (on its own, in a preparation or incorporated into an article) by a manufacturer, importer or downstream user unless: (a) that use has been authorised (the discussion above); or (b) that use is exempt from authorization.⁸⁰ However, substances on the Annex XIV authorisation list may still be used for scientific research and development or (in certain situations) product and process orientated research and development.⁸¹ As for exempt uses, inclusion of substances in Annex XIV does not apply to:

- (a) uses in plant protection products within the scope of Directive 91/414/EEC;
- (b) uses in biocidal products within the scope of Directive 98/8/ EC;
- (c) use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels; and
- (d) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.⁸²

The first three of these arguably exist because of overlapping protections in other areas of EU law, but the fourth is more curious and may have been the result of sectoral industry lobbying during the negotiations of REACH.

In addition, Article 56(5) details that in the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) (that is, CMRs) or because they are identified in accordance with Article 57(f) (the

⁸⁰ Article 56(1)

⁸¹ Article 56(3)

⁸² Article 56(4)

equivalent concern provision) only because of hazards to human health, inclusion in the Annex XIV authorisation list does not apply to the following uses:

(a) uses in cosmetic products within the scope of Directive 76/768/EEC;

(b) uses in food contact materials within the scope of Regulation (EC) No 1935/2004.

The preceding discussion has reviewed the Authorisation process under REACH. The following discusses Restriction. As outlined in the introduction to this Chapter, these two processes are fundamentally similar (having identical common aims of chemical risk management via forms of substance bans) but operate quite differently on a practical level.

Restriction

ECHA comments that, "...restriction is designed as a "safety net" to manage risks that are not addressed by the other REACH processes."⁸³ The thinking (whatever the drafting of REACH and the opinions of the Member States, on which see below) is that Restriction will be a regulatory response of last resort for the most harmful of substances for which urgent action is necessary. The Restriction process under REACH takes the place of previous EU legislation on chemical risk management, and substances which were already banned (in full or in certain applications) under pre-REACH EU law⁸⁴ (such as asbestos fibres, mercury, arsenic etc.) have been grandfathered into Annex XVII of REACH (the "Restriction List.")⁸⁵ In this context, it is worth replicating Recital 84 of REACH in full:

"In order to accelerate the current system the restriction procedure should be restructured and Directive 76/769/EEC, which has been substantially amended and adapted several times, should be replaced. In the interests of clarity and as a starting point for this new accelerated restriction procedure, all the restrictions developed under that Directive should be incorporated into this Regulation. Where appropriate, the

⁸³ ECHA, 'ECHA Opens Web Pages on Restriction' (News Alert, 5 November 2009, ECHA/NA/09/27)

⁸⁴ As contained in the so-called 'Limitations Directive (which is discussed in more depth in Chapter 1)

⁸⁵ Recital 84 Article 139 repeals Directive 76/769/EEC as from 1 June 2009.

application of Annex XVII of this Regulation should be facilitated by guidance developed by the Commission.”

From this recital, two points are worth making. The first is that Restriction under REACH is supposed to be an ‘acceleration’ of previous approaches to substance bans. This seems somewhat at odds with Authorisation and the fact that, according to ECHA, “restrictions normally address concerns which are in one way or another exceptional.”⁸⁶ The second is that Recital 84 contains one of the few explicit references in REACH to the production of specific guidance. Here, we are told that the Commission will develop guidance to ‘facilitate’ the application of the Restriction List. While there is guidance on Restriction (see below), this has come from ECHA and not the Commission (and it is not at all clear where or how the Commission delegated this guidance making power to the Agency.)

In the context of how Restriction operates vis-à-vis authorisation, Article 3(31) of REACH details that Restriction means “any condition for or prohibition of the manufacture, use or placing on the market”. On this reading, one would be forgiven for confusing the Restriction process with the Authorisation process, as both seek to limit the ability to manufacture, use or place on the market certain chemical substances. At the same time, the text of the REACH does not differentiate particularly well between the two processes. Aside from Article 58, which details that certain substances which have been included in the Annex XIV Authorisation List should not then undergo Restriction, REACH is silent in this regard. Recital 80 to the Regulation details that:

“The proper interaction between the provisions on authorisation and restriction should be ensured in order to preserve the efficient functioning of the internal market and the protection of human health, safety and the environment.”

However, there is no guidance in the text as to what “proper interaction” may mean. Let us take one example. There are currently four phthalates on the Candidate List. However, there have been calls for six phthalates (including three

⁸⁶ ECHA (n 28) 38

of those on the Candidate List) to be restricted under REACH.⁸⁷ This dual approach seems a waste of regulatory resources.

ECHA has acknowledged the issues with the interface between Authorisation and Restriction in their first official report on the operation of REACH. They comment that, while in certain circumstances, it would be possible to have both Restriction and Authorisation operating at the same time, “there may be reasons not to initiate the two procedures in parallel for the same substance, e.g. the effective use of resources in authorities and industry, legal clarity and predictability.”⁸⁸ What is clear, at least from the recitals to REACH, is that the primary onus for the risk management of the most harmful chemicals in the EU is supposed to be on the private sector. As detailed above, Restriction under REACH is seen as the last resort. Here, Recital 86 details that:

“It should be the responsibility of the manufacturer, importer and downstream user to identify the appropriate risk management measures needed to ensure a high level of protection for human health and the environment from the manufacturing, placing on the market or use of a substance on its own, in a preparation or in an article. However, where this is considered to be insufficient and where Community legislation is justified, appropriate restrictions should be laid down.”

How and when a regulator would know that risk management by the private sector of the most harmful chemicals is “insufficient” is not set out. Having discussed background, the following sections set out the practical operation of restriction.

Title VIII – How Restriction Works

Title VIII of REACH contains the provisions relating to the restriction of substances. Article 67 details that those substances listed in the Annex XVII Restriction List cannot be manufactured, placed on the market or used unless they comply with the conditions of the relevant restriction. Using substances on the Restriction List in cosmetics or for scientific research and development is permitted, as is, in certain instances, using those substances for product and

⁸⁷ See: <http://ec.europa.eu/enterprise/sectors/chemicals/files/markrestr/phth-com-pos-pap_en.pdf> accessed 10 August 2014

⁸⁸ ECHA (n 28) 33

process oriented research and development.⁸⁹ Any decision to add a substance onto the Restriction List must, “take into account the socio-economic impact of the restriction, including the availability of alternatives.”⁹⁰

As with authorisation, the process by which a substance is added to the Restriction List is highly technical, as well as being somewhat protracted and tortuous.⁹¹ As with authorisation, the process begins with the preparation of a dossier (here, a ‘restriction’ dossier that complies with the requirements of Annex XV of REACH – on which, see below). As with authorisation, the dossier is prepared either by ECHA (following a request by the Commission) or by a Member State.⁹² Article 69(1) of REACH details that the Commission is obliged to request an Annex XV restriction dossier from ECHA where the Commission,

“considers that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed.”

This wording in the Regulation is vague (especially in the context of ‘adequate control’) and leaves great discretion to the Commission. Similar wording appears in relation to the preparation of dossiers by Member States.⁹³ What is noteworthy here is the lack of any reference to SVHCs. Unlike Authorisation, where the identification of a SVHC is a pre-requisite, the Restriction process under REACH in the context of dossier preparation simply refers (save for one isolated example below) to substances posing risks that are “not adequately controlled”. What this means then is that, in theory, Restriction under REACH could address a much wider range of harmful substances than under Authorisation.

The only time at which the Restriction process set out in REACH does cross reference the notion of a SVHC is in Article 69(2), which grants ECHA the power to prepare a restriction dossier, of its own initiative, for SVHCs in articles which

⁸⁹ Article 67(1) and (2)

⁹⁰ Article 68(1)

⁹¹ This being said, Article 68(2) does contain a form of “super charged” restriction for CMRs which are used by consumers. In this context, Article 68(2) details that Articles 69 to 73 (which contain the procedural hoops for restriction) do not apply and that the relevant substances can be included in the Restriction List simply by decision of the Commission.

⁹² Article 69(1), (4)

⁹³ See Article 69(4)

are on the Authorisation List and for which the sunset date has expired (i.e. for SVHCs in articles which can no longer be manufactured or placed on the market without specific authorisation under REACH.)⁹⁴ This is a much narrower power and sits somewhat oddly with the other Restriction provisions: (a) in that it is a power granted to ECHA alone to prepare a dossier (and not to the Member States); and (b) because of the reference to SVHCs.

In order to prevent overlap and duplication of work, Member States are required to notify ECHA of their intentions to prepare an Annex XV dossier for a restriction.⁹⁵ ECHA is, in turn, obliged to maintain a public ‘registry of intentions’ which details the notifications it has received from the Member States.⁹⁶ Where the Commission asks ECHA to prepare an Annex XV restriction dossier, and where this dossier details that, “Community wide action is necessary”, ECHA is obliged to suggest restrictions within 12 months of the initial request.⁹⁷ Where the restriction dossier is to come from a Member State, that State has 12 months (from the date of notification of its intention to produce the dossier) to submit the dossier to ECHA.⁹⁸

RAC and SEAC Review of the Restriction Dossiers

Following the preparation of the restriction dossier, the second step in the Restriction process involves the checking of the restriction dossier by the RAC and the SEAC. This is akin to the completeness check undertaken in Registration (that is, this check does not look to substance, but simply to form, the relevant question being: does the dossier comply with the requirements set out in Annex XV?)⁹⁹ It is worth noting that this process of verification by the RAC and SEAC does not also occur with the Annex XV SVHC dossiers that are the first step in the Authorisation process. Restriction dossiers which pass the RAC/SEAC check are then published on ECHA’s website, after which follows a six month public

⁹⁴ Article 69(2)

⁹⁵ Article 69(4)

⁹⁶ Article 69(5); see: <http://echa.europa.eu/chem_data/reg_intentions_en.asp> accessed 10 August 2014

⁹⁷ Article 69(3)

⁹⁸ Article 69(4)

⁹⁹ Article 69(4)

consultation on the contents of the dossier.¹⁰⁰ Article 69(6) details that, as part of the consultation, interested parties can submit a, “a socio-economic analysis, or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.”

Within 9 months of the publication of the dossier on ECHA’s website, the RAC is obliged to provide an opinion on the dossier. Article 70 details that the opinion, “shall take account of the Member State dossier or of the dossier prepared by the Agency at the request of the Commission, and the views of interested parties [resulting from the public consultation]”. What this means as a matter of practice is that the RAC has three months following the end of the public consultation to consider the data generated by that consultation and feed that data in to the production of its opinion on the dossier. The text of REACH does not specify any obligation for a public consultation on the RAC opinion. Such, however, is required for the opinion produced by the Committee for Socio Economic Analysis (“SEAC”), which is required within 12 months of the publication of the dossier on the ECHA website.¹⁰¹ No reason is given, either in the text of REACH or in associated guidance, as to: (i) why the SEAC is given an extra three months for the preparation of its opinion (compared to that of the RAC); or (ii) why the SEAC opinion (and not the RAC opinion) is subject to public review. ECHA has called for these differences to be regularised.¹⁰²

Three months after the restriction dossier is published on the ECHA website, a rapporteur from each of the RAC and the SEAC meets with the party that submitted the dossier (that is, ECHA or the relevant Member State) to discuss the contents of the dossier.¹⁰³ This meeting is not detailed in the text of REACH, but there are obvious practical benefits in the submitting party and the two committees meeting and sharing information. However, what this means is that for data submitted as part of the public consultation to be discussed during this meeting, that data needs to be submitted within the first three of the overall six month

¹⁰⁰ Article 69(6)

¹⁰¹ Article 71(1)

¹⁰² ECHA (n 28) 39

¹⁰³ See: <<http://echa.europa.eu/addressing-chemicals-of-concern/restriction>> accessed 10 August 2014

consultation window. A previous iteration of the ECHA website contained the advice that, “it is highly recommended to give comments within the first three months of the consultation period.” The current website however, states,

“The public consultation lasts for six months...Provide your comments within the first three months of the consultation period to ensure that your comments are taken into account when the rapporteurs of ECHA's Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC) meet three months after the publication of the proposal.”¹⁰⁴

While the practical benefits of this advice are obvious (and the Committees have little time in which to produce their reports), the exhortation from ECHA that the public provides their comments “within the first three months” goes against the text of Article 69(6) which very clearly states that, “The Agency shall invite [comments from] all interested parties to submit individually or jointly within 6 months of the date of publication [of the dossier].” This, it is suggested, is a clear example of ECHA translating the text of REACH into something other.

Once drafted, ECHA publishes the opinions from the RAC and SEAC on its website and on forwards them to the Commission for review.¹⁰⁵ Following receipt of the RAC and SEAC opinions, if the Commission is of the view that, “there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis,”¹⁰⁶ it has three months in which to prepare an amendment to Annex XVII: that is, three months to prepare a Commission regulation which would add the relevant substance to the Restriction List.¹⁰⁷ This language of “unacceptable risks” in Article 68(1) is different to that in Article 69 (which empowers the Commission to call for a restriction dossier). As set out above, in Article 69 the Commission is allowed to call for a dossier where the risk from the substance is “not adequately controlled and needs to be addressed”. This mismatch in language is not discussed in guidance produced by ECHA on the restriction process (on which, see below).

¹⁰⁴ *ibid*

¹⁰⁵ Article 71(1) and (2)

¹⁰⁶ Article 68(1)

¹⁰⁷ Article 73(1)

The final decision on including the substance in the restriction dossier in the Restriction List is taken via the standard comitology procedure with scrutiny.¹⁰⁸ In short, if the Council and the European Parliament do not oppose the suggested restriction, the Commission adopts it. Thereafter, the amendment to the Restriction List set out in Annex XVII is published in the Official Journal.

The Restriction Dossier

As detailed above, the Restriction process begins with the preparation of a dossier that complies with the requirements of Annex XV. However, the text of Annex XV setting out those requirements is both vague and limited. ECHA has called for “clarification” as regards the necessary information needed, particularly as regards the data required in the discussion of the cost of a restriction and other socio economic information.¹⁰⁹

In June 2007, ECHA issued guidance on the preparation of an Annex XV restriction dossier (hereafter, the “Restriction Dossier Guidance.”)¹¹⁰ In it, the Agency comments that “Annex XV...lays down general principles for preparing dossiers to propose and justify restrictions.”¹¹¹ Much of the Restriction Dossier Guidance is technical in nature, providing detail on the preparation and content of the restriction dossier. Compared to the text of REACH, the guidance is expansive: 130 pages and more than 40,000 words compared to the 5 pages and 773 words of Annex XV.

The Restriction Dossier Guidance details a list of non-exhaustive “triggers” which may prompt Member States to begin the process of creating a restriction dossier. These, it is submitted, perform an amplification function and expand on the bare bones of Annex XV. The triggers include, “substances having a wide range of uses associated with multiple exposures”, “substances which may be widely used by consumers in several applications and for which the conditions of safe use cannot

¹⁰⁸ Articles 73(2) and 133(4)

¹⁰⁹ ECHA (n 28) 38

¹¹⁰ ECHA (n 5)

¹¹¹ *ibid*, 9

be ensured” and “where there are a number of available Chemical Safety Reports for one substance.”¹¹² In addition, the guidance details that the restriction dossier process might be started by a Member State as a result of the REACH Evaluation process. However, as discussed in Chapter 6, Evaluation is very limited and is unlikely to lead to a large number of substances registered under REACH being reviewed. At the same time, Restriction, like Authorisation, is supposed to be independent of Registration under REACH. Despite this, in the Restriction Dossier Guidance, ECHA acknowledges that “The amount of information available to an Authority when beginning the preparation of an Annex XV dossier will, therefore, depend on the status of the substance in REACH [i.e. whether it has been registered or not], and this may have an influence on the development of the dossier.”¹¹³

These example triggers (and the others set out in the guidance) are based in a good deal of presumption: presumption about the effective operation of the Evaluation process; presumption about proactive review by Member States of registration dossiers; and presumption about REACH enforcement mechanisms. The extent to which Member States will actively go looking for data on which to base a restriction dossier is questionable. As noted above, Restriction is a “safety net”, designed to address unacceptable risks. Given this, the fact that preparation of restriction dossiers is so dependent on registration timelines and on the imperfect information generated by the private sector via Registration is concerning. In particular, where a substance will not undergo Registration, Member States, ECHA and the Commission are likely to have a much more limited data set on which to draw. Take, for example, certain nanosubstances. As discussed above, it is unlikely that many of these will undergo registration and yet concerns exist about their impact on human health and the environment. A Member State thinking such substances might pose unacceptable risks on a Community wide basis would have a difficult time sourcing relevant literature on which to base a restriction dossier.¹¹⁴ We might then question the effectiveness of Restriction as a substance risk management process. Even though Restriction is possible for a

¹¹² ECHA (n 5) 14-15

¹¹³ ECHA (n 5) 16

¹¹⁴ For a wider discussion of this issue, see: Lee and Vaughan (n 2)

substance which has not undergone Registration, the likelihood this will be happen as a matter of practice seems small indeed given the practical difficulties in creating the relevant restriction dossier.

Annex XV is silent on whether those preparing restriction dossiers should consult with those who might be affected. Despite this, the Restriction Dossier Guidance comments, that “stakeholder involvement in the [dossier preparation] process is important” and details that, “Authorities are encouraged to engage stakeholders and other interested parties in the development of the dossier as early in the process as possible.”¹¹⁵ Similar advice, it will be recalled, was also given by ECHA in the context of consultations on authorisation dossiers.

Socio Economic Analysis

There is no obligation under REACH on a party proposing a restriction to include a socio economic analysis (“SEA”) of that restriction.¹¹⁶ However, a SEA may be included in the restriction dossier. If it is so included, ECHA comment that the SEA would be, “used in the decision making process (by the SEA Committee and the European Commission) to assess the benefits and costs of the proposed restriction.”¹¹⁷ The information which a SEA might address (if it is included) is set out in Annex XVI of REACH. This Annex is one page long and made up of 476 words. Annex XVI details that “The Agency shall prepare guidance for the preparation of SEAs.” This is one of the few specific instances in the text of REACH in which ECHA is mandated to produce guidance (rather than, as seen in the recitals to REACH, generic comments as to the utility of guidance). The guidance produced by ECHA, “Guidance on Socio Economic Analysis: Restrictions” (hereafter, the “SEA Restriction Guidance”), in May 2008 is 211 pages long and contains just under 80,000 words. Unlike many of the other guidance documents produced by ECHA, the SEA Restriction Guidance has not been updated since its publication.

¹¹⁵ ECHA (n 5) 22

¹¹⁶ Annex XV simply states, “The socio economic impact of the proposed restriction *may* be analysed with reference to Annex XVI” (own emphasis).

¹¹⁷ ECHA (n 8) 20

The SEA Restriction Guidance highlights that if Member States want ECHA's Committees for Risk Assessment to SEA to act quickly in response to a Restriction proposal, then the Member State needs to submit "a good quality Annex XV dossier."¹¹⁸ As noted above, a SEA in a restriction dossier is not necessary as REACH is drafted. However, the SEA Restriction Guidance comments, after stressing the tight deadlines in which the Commission needs to make a restriction decision and the need for the restriction dossier to contain sufficient information to give the Commission a basis to decide that restriction is appropriate, that, "although not compulsory, Member States or the Agency preparing a restriction proposal should seriously consider analysing the socio-economic impacts to support the restriction proposal"¹¹⁹. Given this language, and the associated framing of the issue, it is suggested that the SEA Restriction Guidance makes the inclusion of a SEA in an Annex XV an absolute (practical if not legal) requirement if that dossier is to lead to a restriction. This is almost certainly the view held by Geert Dancet, ECHA's Executive Director, who commented that, "socio-economic analysis is an integral part of the preparation of a restriction dossier."¹²⁰ This is another example of ECHA creating an effective obligation on Member States (and itself) where REACH is silent, and so is another example of extrapolation.

The SEA Restriction Guidance details that there are five stages to the preparation of a SEA. These are, as one would expect, identical to the stages set out above in the SEA Authorisation Guidance. Hence, the first is to set out the aims of the SEA; the second to set the scope of the SEA; the third to identify and assess the impacts of a restriction; the fourth to interpret the data and draw conclusions; and the fifth to present the results of the SEA.¹²¹

SEA appears an enormously difficult task. For the party proposing a restriction, ECHA details that they will,

¹¹⁸ ECHA (n 8) 25

¹¹⁹ *ibid*

¹²⁰ ECHA, 'Applying socio-economic analysis as part of restriction proposals under REACH' (Workshop Proceedings, Helsinki, 21 – 22 October 2008) 12

¹²¹ ECHA (n 8) 30ff

“need to decide whether it is possible to draw a robust conclusion concerning the proposed restriction when assessing the net benefits to human health and the environment and the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.”¹²²

This seems an onerous task and a high benchmark, the practical consequence of which means that it is likely that few Member States will be confident enough to put forward an Annex XV restriction dossier. At the same time, however, ECHA also seems to suggest that it may not be possible to have an overly detailed SEA:

“In general the Authority should seek to build as robust a case as possible, but as there are limited resources available to develop SEAs, the level of detail should be proportionate to the problem in hand.”¹²³

These tensions, the need for a robust SEA versus practical limitations on Member State resources, are apparent throughout the SEA Restriction Guidance. They do not sit well together and make the guidance appear, at times, dislocated. At a workshop organised by ECHA on SEA and held in Helsinki in October 2008 (hereafter, the “SEA Workshop”),¹²⁴ one of the “main conclusions” was that, “SEAs will not be perfect. We will need to learn to live with imperfect information.”¹²⁵

Despite being 211 pages long, the SEA Restriction Guidance is strikingly vague in places. One might argue that such is appropriate, given that guidance should not usurp the role of the text of REACH. However, the SEA Restriction Guidance is a good illustration of where ECHA attempts to channel the behavior of those subject to REACH without sufficient specificity to make the guidance meaningful in any real way. Take, for example, the advice in relation to the identification and assessment of “social impacts” in a SEA:

“Social impacts: These are all relevant impacts which may affect: workers, consumers, and the general public and which are not covered under health, environmental or economic impacts [which are themselves vague and lacking in detail] (e.g. employment, working

¹²² ECHA (n 8) 32

¹²³ ECHA (n 8) 44

¹²⁴ With 100 participants from, among others, the RAC, SEAC, Member State Competent Authorities, European Commission, ECHA and the US Environmental Protection Agency.

¹²⁵ ECHA (n 121) iv

conditions, job satisfaction, education of workers and social security). Impacts on certain social groups may need to be considered.”¹²⁶

While this inherent vagueness may be deliberate, and an attempt to give Member States flexibility in creating a SEA, it may lead to practical issues in the creation of the Annex XV restriction dossier. At other times, the guidance is strikingly detailed (for example, as regards the monetisation of human health impacts via “willingness to pay” values.)¹²⁷ What is clear is that the SEA Restriction Guidance implicitly favours quantitative over qualitative assessment of impacts and is much more detailed when the assessment of impacts can be reduced to mathematical formulae.¹²⁸ Interestingly, one of the “main conclusions” of the SEA Workshop goes completely against the tenor of the guidance in this regard: “In many occasions, well-prepared qualitative assessments may be the end result. A full-blown quantitative assessment is unlikely to be prepared due to lack of information and data.”¹²⁹ The tenor of the SEA Restriction Guidance in this regard provides a good example of ECHA’s advice determining a significant plank of the operational framework of REACH: in this instance, a seeming preference for quantitative over qualitative data.

As well as having differing precision in the delineation of impacts, the SEA Restriction Guidance also creates a hierarchy as regards the materiality of different impacts:

“The human health, environmental and economic impacts are often the most significant and therefore should be assessed first. Analysis of social and wider economic impacts should follow on...”¹³⁰

Nowhere is this hierarchy of significance to be found in the text of REACH. In particular, Annex XVI of the Regulation (“Socio Economic Analysis”) simply lists, without preference or rank, the types of impacts which might be included in a SEA. While the lack of ranking of impacts in the text of REACH may be a matter worthy of future reform (in that it would be useful to know which impacts should take preference over others), it is questionable whether ECHA has the right to be

¹²⁶ ECHA (n 8) 41

¹²⁷ ECHA (n 8) 82ff

¹²⁸ ECHA (n 8) 78ff

¹²⁹ ECHA (n 121) iv

¹³⁰ ECHA (n 8) 41

so categorical in its SEA Restriction Guidance. This is another example of ECHA translating the text of REACH as it sees best.

Restrictions to Date

As of 18 September 2013, 20 substances have been put forward for consideration for restriction: two nominated by France (both in April 2010), five by Norway (in June 2010), five by Denmark (in April 2011 and January); two by ECHA (in June 2010 and April 2012); five by Sweden (in August 2012, January 2013 and July 2013); and one by the Netherlands (in August 2013).¹³¹ The nominee substances appear somewhat uncontroversial (in that they seem to be ‘known’ harmful chemicals) and include: dimethylfumarate (for which there is already a temporary ban in place);¹³² lead used in jewellery (due to children being poisoned via ingestion);¹³³ phenylmercury compounds (which degrade and are highly toxic to humans, ecosystems and wildlife);¹³⁴ and mercury used in measuring devices.¹³⁵ In terms of the quality of the restriction dossiers put forward for consideration, ECHA has commented that “The focus and details of restriction reports vary from case-to-case and it remains a challenge to prepare a high quality dossier which is proportionate to the case in question.”¹³⁶

Conclusions

This Chapter has done two things. First, it has provided a critical review and comparison of the Authorisation and Restriction processes under REACH. Second,

¹³¹ See: <<http://echa.europa.eu/addressing-chemicals-of-concern/restriction> > accessed 10 August 2014

¹³² See: <http://echa.europa.eu/doc/restrictions/annex_xv_restriction_report_DMFu_en.pdf> accessed 10 August 2014

¹³³ See: <http://echa.europa.eu/doc/restrictions/annex_xv_restriction_report_lead_en.pdf> accessed 10 August 2014

¹³⁴ See: <http://echa.europa.eu/doc/restrictions/annex_xv_restriction_report_phenylmercury_compounds_en.pdf> accessed 10 August 2014

¹³⁵ The use of mercury in measuring devices for the general public is already prohibited (see entry 18a, Annex XVII, REACH). This proposal for restriction relates to measuring devices used in healthcare and other professional and industrial contexts. See: <http://echa.europa.eu/doc/restrictions/annex_xv_restriction_report_mercury_en.pdf> accessed 10 August 2014

¹³⁶ ECHA (n 24) 38

it has considered how guidance produced by ECHA shapes the operation of these two processes.

Authorisation and Restriction are highly technical and highly structured processes. They are, at the same time, both built on a number of assumptions and on the data which has been, and will be, generated via Registration. This is despite the fact that both Authorisation and Restriction are supposed to operate independently and irrespective of Registration. The two processes share the same regulatory goal: the inability to manufacture or place on the market a particular substance (either in full or in part). However, Authorisation is somewhat narrower than Restriction, as the former only applies to substances that are SVHCs. In addition, a number of uses (e.g. medicinal products, food) are specifically excluded from the Authorisation process, but which could be regulated under Restriction if the need arose.

One key difference between the two processes is that applications can be made for specific, permitted uses of the regulated substance under Authorisation, which is not permitted under Restriction. However, with Restriction, it is possible for a Member State (or ECHA) to wrap a form of authorisation into the restriction by only restricting certain uses of the substance in certain contexts (and thereby implicitly authorising the use of the substance in all other contexts). The second key difference is that Restriction is, in theory, quicker and for substances of most concern. That being said, regulatory action to date under both Authorisation and Restriction has been slow. In their review of REACH, ECHA commented that restrictions are “relatively heavy to introduce” and there seems to be little appetite for wide scale activity by either the Agency or Member States.¹³⁷

This Chapter has highlighted a number of practical issues with the day-to-day workings of Authorisation and Restriction, including: the lack of clarity on the overlap between the two processes; the lack of obligations on registrants to actively highlight potential SVHCs to ECHA; the limited time which the RAC and SEAC have to make their decisions; and the limited resources which Member States have thus far brought to bear on targeting chemicals of concern.

¹³⁷ ECHA (n 24) 39

The guidance produced by ECHA for Authorisation and Restriction is long, dense and highly technical, more so for Restriction than for Authorisation. Compared to the other aspects of REACH previously explored in this thesis, with ECHA's guidance on Authorisation and Restriction we see many more clear examples of the Agency shaping the operation of the Regulation either: (a) in ways not foreseen or set out in REACH (the extrapolation function); or (b) in ways that are contrary to the legislation (the translation function). As regards the former, this Chapter has highlighted the following examples:

- (i) The advice that Member States engage in public consultation during the preparation of an SVHC dossier (where REACH is silent on consultation at this stage of the process);
- (ii) The creation of a hierarchy of human health, environmental and socio-economic impacts as part of Socio Economic Analysis (where REACH has no such hierarchy);
- (iii) The favouring of quantitative over qualitative data for socio economic analysis (which is not set out in the Regulation);
- (iv) The detailing of triggers for Member State action to restrict substances (where REACH is silent on what may prompt regulatory action in this area); and
- (v) The (strong) suggestion that applicants for authorisation include a socio economic analysis even where they are seeking authorisation on the basis of 'adequate control' (and where REACH does not say that SEA is required).

Such shaping and channeling by ECHA means that the Agency is itself creating significant planks in the practical operation and implementation framework of REACH. As regards direct contestation (the 'translation' function of ECHA's guidance), the text of REACH is very clear that there should be a six month period

of public consultation on restriction dossiers.¹³⁸ Despite this, ECHA is equally clear in its advice to the public that they should, “Provide [their] comments within the first three months of the consultation period to ensure that [their] comments are taken into account.”¹³⁹ Looking back, this thesis has thus far explored the main processes under REACH: Registration; Evaluation; Authorisation; and Restriction. The Chapter which follows looks at the enforcement of the Regulation.

¹³⁸ Article 69(6)

¹³⁹ ECHA (n 103)

CHAPTER 8

THE ENFORCEMENT OF REACH

As a Regulation, REACH is directly applicable in every Member State without the need for transposition into national law.¹ However, the enforcement of REACH is a matter for individual Member States, who are required to “maintain a system of official controls and other activities as appropriate to the circumstances.”² What this means, in practice, is that it is for individual Member States to set out provisions on the sanctions associated with the infringement of REACH (in their respective jurisdictions) in their national laws. Such penalties must be “effective, proportionate and dissuasive” and notification to the Commission of the national REACH enforcement regimes was required by 1 December 2008.³

28 separate regimes for the enforcement of REACH across the EU could easily lead to claims of disproportionate or discriminatory impact. Given this, REACH does provide for some attempts at co-ordination (if not harmonisation) in this area at the EU level. This Chapter is concerned with the mechanics of REACH enforcement in the UK and with the inter-relationships between the REACH regulatory agencies in the UK *inter se* and with ECHA, in both cases as set out in the text of the Regulation as well as in associated guidance (here, by ECHA’s Enforcement Forum and by the UK’s Health and Safety Executive). As was noted in Chapter 3, the REACH enforcement regime in the UK has been chosen as the most appropriate focus for obvious reasons. This Chapter does not discuss the overlap of REACH enforcement issues with EU Regulation 765/08 on Accreditation and Market Surveillance, a matter of some concern for the Dutch Government.⁴ Instead, this Chapter begins with an overview of the attempts at EU

¹ Article 288 TFEU

² Article 125, REACH. As in other Chapters, save as expressly stated otherwise, references in this Chapter to “Articles” and “Recitals” are references to Articles and Recitals of REACH.

³ Article 126. As at 1 December 2008, only 14 out of 27 Member States had notified the Commission of the national provisions for breach of REACH. By September 2009, it was reported that 4 Member States (Austria, Belgium, Italy and Portugal) had still not notified the Commission – see: <<http://chemicalwatch.com/2659>> accessed 10 August 2014

⁴ See: <<http://chemicalwatch.com/2433>> accessed 10 August 2014

REACH enforcement co-ordination before turning, in some detail, to the UK regime contained in the REACH Enforcement Regulations 2008.

REACH Enforcement Co-Ordination at the EU Level

At the EU level, a Forum for Exchange of Information on Enforcement (hereinafter, “the Forum”) was established as part of ECHA, with the aim of coordinating a network of the Member States’ authorities responsible for REACH enforcement.⁵ The Forum has no enforcement powers itself and is not a regulatory body. Rather, it has a series of given tasks (as set out in Article 77(4) of REACH) of a more general nature, including spreading good practice, highlighting enforcement problems at Community level and proposing, coordinating and evaluating harmonised enforcement projects and joint inspections.⁶ It is worth noting that the language used in Article 77(4) refers to “good practice”, “working methods” and “coordination” but does not explicitly refer to ‘guidance’ (as happens elsewhere in the text of REACH). The need for such a Forum is put fairly clearly in Recital 105:

“In the light of the increased responsibility of natural or legal persons for ensuring safe use of chemicals, enforcement needs to be strengthened. The Agency should therefore provide a Forum for Member States to exchange information on and to coordinate their activities related to the enforcement of chemicals legislation. The currently informal cooperation between Member States in this respect would benefit from a more formal framework.”

What is not said in the text of REACH, but which is equally obvious, is that there must be fair and consistent enforcement of REACH across the 28 Member States. Without this, certain companies in certain Member States could be put at a significant competitive disadvantage.⁷

Membership of the Forum is comprised of one representative per Member State (chosen “for their role and experience in enforcement of chemicals legislation”),

⁵ Article 76(1). The Forum also has responsibility for co-ordinating the enforcement of the CLP Regulation. However, and as stated in Chapter 1, the CLP Regulation is outside the scope of this thesis.

⁶ Article 77(4)(a) and (b)

⁷ DEFRA, ‘Summary of responses to the consultation on REACH enforcement between 13 March to 4 June 2007’ (Department for Environment, Food and Rural Affairs, August 2007)

with an additional 5 co-optees, who are invited to join the Forum to enable it to have a “broad range of relevant expertise among its members.”⁸ Forum members are appointed for a three year term. The current UK representative on the Forum is Mike Potts, Senior Scientific Officer within the REACH section of the UK Health and Safety Executive.⁹ Member State representatives in the Forum are required to ensure that there is “appropriate coordination” between the Forum and the REACH competent authorities in their respective States.¹⁰ Exactly what would count as “appropriate” co-ordination and what would fall outside this term is not given and is unclear. While it is intended that the Forum is to be supported, on a technical and scientific level, by resources in individual Member States,¹¹ the Forum is allowed to seek external advice “on important questions of a general scientific or ethical nature.”¹² Given the differences among Member States as regards their technical and scientific resources (and their appetite for REACH enforcement), it may be that certain States shoulder more responsibility for supporting the Forum than others.¹³

In February 2009, the Forum adopted Rules of Procedure,¹⁴ which deal with internal mechanical matters including, but not limited to, the election of a Chair of the Forum, the allocation and casting of votes and the recording of meeting minutes. Of more importance is the Forum’s Work Programme, required under Article 2(4) of the Rules of Procedure. In creating a specific Work Programme (which is updated annually), the aim is to, “cover the tasks as described in...[REACH and the Forum’s Rules of Procedure]... structured into suitable work packages to be handled by working groups or otherwise, [while] also trying

⁸ Article 86(1)

⁹ The role of the HSE in relation to REACH enforcement is discussed in more depth later on in this Chapter. A full CV of Mr Potts can be found here: http://echa.europa.eu/documents/10162/13577/forum_mini_cv_potts_en.pdf accessed 10 August 2014

¹⁰ Article 86(2)

¹¹ Here, the exact level of support is not specified in the text of the Regulation. Article 86(3) details that “Each Member State competent authority shall facilitate the activities of the Forum and its working groups” but the lack of specificity gives rise to the potential for disparate support across the EU.

¹² Article 76(3)

¹³ The author is aware, from contacts in the chemicals sector, that the UK strongly pushed for the Forum and is taking the lead on many of the Forum’s initiatives.

¹⁴ See: http://echa.europa.eu/documents/10162/13577/forum_procedures_rules_en.pdf accessed 10 August 2014

to avoid unnecessary overlap of work”.¹⁵ Interestingly, the first matter in the Work Programme for 2008–2010 is not, as might be have been thought, a common strategy for the enforcement of REACH, but rather the task of agreeing on a common format for the report that each Member State is required to submit every five years to the Commission (under Article 117) on the enforcement of REACH.¹⁶ Article 77(4) of REACH sets out 8 tasks for the Forum. These are not ranked and no guidance is given in the Regulation on whether one is more important than any other. Despite this, the Work Programme has priority settings, such that certain tasks (e.g. developing an electronic information exchange system) are less urgent than others (e.g. enforcement co-ordination projects).¹⁷ This is a clear example of ECHA (through its Enforcement Forum) translating the text of REACH into something not seen in the Regulation (here, take a list of non-hierarchal tasks and putting them into priority ordering). Unlike other examples of ‘translation’ seen in previous Chapters, however, in this instance the guidance comes not really from agents of the Agency but from Member States (via their nominees sitting on the Forum).

The Work Programme also foresees the issuing of guidance by the Forum where this will allow it to, “document good practice.”¹⁸ When this guidance will be issued is another matter. In May 2008 the Forum decided that, “REACH enforcement guidance should be elaborated once enforcement experience is gained on specific areas, as a result of performing coordinated projects.”¹⁹ One piece of guidance has now been issued, on complaints handling under Article 33(2).²⁰ This is a good example of the amplification of the text of REACH, in that it provides advice to registrants and Member State competent authorities but specifically states that there is no need for a “specific route” of complaints handling to be set out. The current Work Programme (2011-2013) details that other guidance is also

¹⁵ ECHA, ‘Revised Work Programme 2011– 2013’ (2011) 4. See: http://echa.europa.eu/documents/10162/13577/forum_work_programme_2011-2013_en.pdf accessed 10 August 2014

¹⁶ This Work Programme was housed on ECHA’s website but is no longer publicly available in that space. Copies can, however, be requested from the Agency.

¹⁷ ECHA (n 15) 6-11

¹⁸ ECHA (n 15) 18

¹⁹ ECHA, ‘Forum Work Programme 2008 – 2010’ (2008) Section B.5

²⁰ See: http://echa.europa.eu/documents/10162/13577/guidance_for_handling_complaints_under_article33-2_en.pdf accessed 10 August 2014

in preparation. However, while the Forum's strategy to issue guidance following the results of enforcement coordination projects (discussed below) makes good common sense, for those who are subject to REACH in a number of EU jurisdictions ex post facto guidance (which could be useful for industry in producing a harmonised EU wide REACH compliance policy) is of more limited utility.

From the point of view of the regulated, perhaps the most important aspect of an EU network on REACH enforcement would be some attempt at harmonisation of enforcement policies and approaches across the Member States. However, the Forum admits a certain amount of defeat on this point. In their paper on the "Strategies for Enforcement" of REACH, they comment that,

"Since there is a big difference between Member States in the administrative systems, the type and scale of the industry concerned, the division of competencies and responsibilities of the enforcing authorities, etc., the elaboration of a single, detailed EU wide enforcement strategy...would not be practical."²¹

Instead, the Forum proposes that the "most efficient approach is to elaborate general minimum criteria on the policy, implementation, monitoring and review of the REACH enforcement strategies of the Member States."²² The idea is that the Forum will create a general approach, with detailed strategy the purview of the relevant regulators in the Member States.

The general approach advocated by the Forum in their "Strategies for Enforcement" paper details that the specific enforcement frameworks of each Member State should have five elements: (a) a definition of clear policy objectives and priorities; (b) the right organisational structure for the enforcement of REACH; (c) performing actual enforcement measures; (d) the auditing of progress via monitoring and measurement of the enforcement procedures; (e) the reviewing and updating of the enforcement strategy. One might question the utility of publishing (originally in March 2009) minimum criteria for REACH enforcement

²¹ Forum, 'Strategies for Enforcement' (Adopted at the 9 meeting of the Forum on 1-3 March 2011 and updated from March 2009) 4. See:

<http://echa.europa.eu/documents/10162/13577/strategies_enforcement_reach_2011_en.pdf>

accessed 10 August 2014

²² ibid

three months after the deadline by which Member States were required to notify the Commission of their national systems for REACH enforcement (December 2008).²³ One might also question the value (excluding any aspirational value) of a Forum which has no formal powers and no ability to compel a Member State to do any given thing. Any value in such an organisation will only be apparent where active steps are taken, in a timely fashion, to ensure harmonisation. Only time will tell, as enforcement of REACH is itself in its infancy. Despite these critiques, the “Strategies for Enforcement” paper, while not labelled ‘guidance’, does seem to be attempting to standardise the actions of Member State enforcement practices (albeit at a very high level).

REACH-EN-FORCE-1, or REF-1, was the first coordinated REACH enforcement project initiated by the Forum. National REACH inspectors were to check whether companies had, where so required, submitted pre-registration and/or registration dossiers for phase-in substances. The final report on REF-1 was published in December 2011.²⁴ REF-1 ran from May 2009 to April 2011 and comprised inspections of almost 2,400 companies in 26 Member States.²⁵ REF-1 found higher than expected non-compliance with REACH and noted the need for particular help with SMEs.²⁶ The final report also recommended the need for greater cooperation between Member State competent authorities, particularly when dealing with companies active in several Member States.²⁷ It is not entirely clear what happens next, following the publication of the REF-1 final report. For example, the Forum’s ‘Strategies for Enforcement’ document has not been updated in light of the report, nor has the Forum produced guidance which builds on the recommendations set out in the report. The final report on a second Forum enforcement project, on downstream users (REACH-EN-FORCE-2, or REF-2),

²³ This issue of timeliness appears elsewhere in the work of the Forum. So, for example, a programme to “train the trainers” (i.e. to create a common understanding of REACH enforcement to be fed into the training of REACH inspectors in individual Member States, who would then go on to train others) did not commence until the start of 2010.

²⁴ Forum, ‘Final Report on the First Coordinated REACH Enforcement Project on Registration, Pre-Registration and Safety Data Sheets’ (Helsinki, 31 December 2011). See: <http://echa.europa.eu/documents/10162/13577/forum_ref-1_consolidated_report.pdf> accessed 10 August 2014

²⁵ *ibid*, 2

²⁶ Forum (n 24) 3

²⁷ *ibid*

was published in September 2013.²⁸ Inspections of 1,181 downstream user companies were undertaken, amounting to checks on approximately 6,900 substances, 4,500 mixtures and the evaluation of 4,500 SDSs.²⁹ 67% of those inspected were found to be non-compliant in some way with REACH.³⁰ Despite this, some improvements since REF-1 were noted as regards the format and availability of SDSs.³¹

Before turning to consider the role of ECHA in the context of REACH enforcement, it is perhaps worth noting that the Forum is not the sole enforcement network at the EU level with responsibility for chemicals legislation. While none of the following networks have any specific remit in relation to REACH, their work may impact on the work of the Forum and they are likely to be regulating (or acting in relation to the regulation of) the same businesses:

- The CLEEN network (Chemical Legislation European Enforcement Network), which deals with other legislation on chemicals, such as classification and labeling or biocides;³²
- The SLIC–CHEMEX working group: the SLIC (Senior Labour Inspectors Committee), which deals with labour inspection in the field of health and safety at work and the CHEMEX Working Group, which has been established by SLIC to investigate the impact of REACH on labour inspectors;
- The RoHS enforcement network deals with enforcement of the RoHS-directive;³³
- The IMPEL (European Union Network for the Implementation and Enforcement of Environmental Law) Network, which deals with environmental legislation;³⁴ and

²⁸ Forum, ‘Obligation of Downstream Users – Formulation of Mixtures’ (ECHA-13-R-08-EN, September 2013). See: <http://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf> accessed 10 August 2014

²⁹ *ibid*, 4

³⁰ *ibid*

³¹ Forum (n 28) 5

³² See: <<http://www.cleen-europe.eu>> accessed 10 August 2014

³³ Council Directive (EU) 2011/65 on the restriction of the use of certain hazardous substances in electrical and electronic equipment [2011] OJ L 174

³⁴ See: <<http://impel.eu>> accessed 10 August 2014

- PEMSAC (Platform of European Market Surveillance Authorities for Cosmetics), which deals with cosmetic products.³⁵

ECHA and Enforcement

Exactly what role ECHA has to play in the context of REACH enforcement is not clear. On its website, the Agency comments that,

“ECHA has no enforcement responsibilities, since it is a Community-level institution. However, ECHA does host the Forum for Exchange for Information on Enforcement (Forum).”³⁶

This perhaps belies the lack of clear lines in this area. While ECHA cannot levy sanctions on those subject to REACH, it does have some quasi enforcement-like powers: for example, it may call for more information in relation to a registration dossier or it may reject such a dossier because it does not comply with the relevant requirements under REACH. In their 2008-2010 Work Programme, the Forum commented that,

“Under Article 126 of the REACH Regulation the responsibility for enforcement lies with the Member States. However, the boundaries and interactions between ECHA, [Competent Authority] and [Member State] enforcing authorities need to be clarified. Actions by different institutions in cases of, for example, violations of registration requirements need to be specified.”

The wording of this section has changed in the current (2011-2013) Work Programme, which details that,

“Under Article 126 of the REACH Regulation and Article 46 of the CLP Regulation the responsibility for enforcement lies with the Member States. However, the interlinks and interactions between ECHA, Member State competent authorities (MSCA) and Member State national enforcing authorities (NEAs) need to be clarified. This work is conducted liaising with CARACAL.”³⁷

The two key changes are: (a) a removal of the use of “boundaries”; and (b) the removal of specific reference to registrant violations. A guidance paper by the Forum on the areas of enforcement overlap between ECHA and bodies in the

³⁵ See: <http://ec.europa.eu/consumers/sectors/cosmetics/marketsurveillance/index_en.htm> accessed 10 August 2014

³⁶ See: <<http://echa.europa.eu/regulations/enforcement>> accessed 10 August 2014

³⁷ Forum (n 15) 15

Member States was expected during the course of 2009. The 2011-2013 Work Programme promised the publication of “an inventory of communication cases and needs in enforcement of different obligations” before the end of 2012.³⁸ This has not yet been published.

Before turning to REACH enforcement in the UK, it is also worth stating the obvious: that the Commission has a limited role in REACH enforcement. It plays no role in the enforcement of REACH itself, but does have a role in enforcing compliance by the Member States with their obligations under REACH.³⁹ As noted above, a number of States were late in creating national legislation covering the enforcement of REACH in their respective jurisdictions. It does not appear as if any subsequent enforcement action was taken by the Commission. On the Commission’s website, the only matter of any substance linked to the enforcement of REACH is a report prepared for the Commission on the penalties applicable, in the various Member States, for violations of REACH.⁴⁰ The report detailed striking variations between Member States in the type (criminal, administrative etc) and extent of penalties (from EUR 50,000 to an unlimited fine).⁴¹

The REACH Enforcement Regulations 2008

There is little novelty in the national law introduced by the UK to provide for a system of penalties for the breach of certain of the provisions of REACH. The REACH Enforcement Regulations 2008 (hereafter, the “Enforcement Regulations”) came into force on 1 December 2008, following consultations in the Spring of 2007,⁴² and in the Summer of 2008.⁴³ The following sections discuss the

³⁸ Forum (n 15) 16

³⁹ As the Guardian of the Treaties, the Commission has the option of commencing infringement proceedings under Article 258 TFEU whenever it considers that a Member State has breached Community law.

⁴⁰ See: <http://ec.europa.eu/environment/chemicals/reach/enforcement_en.htm> accessed 10 August 2014

⁴¹ Milieu, ‘Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States’ (Final Report, March 2010). See: <http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/studies/penalties-report_en.pdf> accessed 10 August 2014

⁴² See: <<http://collections.europarchive.org/tna/20090731153943/http://www.defra.gov.uk/environment/chemicals/reach/pdf/reachconsult2007.pdf>> accessed 10 August 2014

various regulators with obligations under the Enforcement Regulations, the structure of the Enforcement Regulations, enforcement activity to date followed by a few words on comparisons of the Enforcement Regulations with other REACH enforcement regulatory schemes across the EU. It is worth stating at the outset that there is no associated guidance to accompany the Enforcement Regulations, either by the Government (and on the DEFRA website) or by the HSE. This is striking, particularly when compared to the wealth of guidance produced by ECHA on REACH.

The Regulators

The Enforcement Regulations provide for a multi-agency approach to REACH enforcement, with certain overlapping areas of remit between the various regulators and a compulsory mandate of inter-agency co-operation and information sharing. It is not surprising that a multi-agency approach has been taken given the breadth of areas on which chemicals legislation touches. Here, the Strategies for Enforcement document produced by the Forum (discussed above) comments that,

“Since [REACH] requires actions to control and manage different requirements in the area of environmental protection, occupational health and safety, consumer protection, customs and the protection of the public from environmental or work related hazards a number of different enforcing authorities are likely to be appointed.”⁴⁴

It is also worth noting that no new REACH enforcement body has been created. Rather, DEFRA was of the view, following their 2007 REACH enforcement consultation, that extending the ambit of regulatory responsibility of existing regulators was the preferred option. For them, such a new body was, “not necessary if the existing regulators can enforce REACH within the range of their current functions.”⁴⁵ This may turn out to be a big ‘if’.

⁴³ See:

<<http://collections.europarchive.org/tna/20090731153943/http://www.defra.gov.uk/environment/chemicals/reach/pdf/reach-enforcement-consultation-document.pdf>> accessed 10 August 2014

⁴⁴ Forum, ‘Strategies for Enforcement’ (March 2011) 4 – see:

<http://echa.europa.eu/documents/10162/13577/strategies_enforcement_reach_2011_en.pdf> accessed 10 August 2014

⁴⁵ DEFRA (n 42) 7

Under the Enforcement Regulations, there are 440 separate regulators, as follows:

- the Health and Safety Executive (HSE);
- the Health and Safety Executive for Northern Ireland (HSENI);
- the Environment Agency (EA);
- the Scottish Environment Protection Agency (SEPA);
- the Northern Ireland Environment Agency (NIEA)
- the Department of Energy and Climate Change (DECC); and
- 434 local authorities (commonly known as ‘trading standards’).⁴⁶

While, in itself, it is not particularly uncommon for the enforcement burden of environmental law in the UK to be shared between different authorities,⁴⁷ this may cause certain issues. Two of the most obvious were put succinctly by the Forum in that, “Each authority is... likely to have different priorities and resources.”⁴⁸ In addition, (and while not explicitly referred to in the Enforcement Regulations), two further regulatory bodies have roles to play in the enforcement of REACH, namely: HM Revenue and Customs (“HMRC”); and the Home Office, as regards the grant and terms of licences for scientific experiments using animals under the Animals (Scientific Procedures) Act 1986. As for HMRC’s role, the HSE comments as follows:

“HMRC will provide assistance to the named enforcing authorities by detaining goods at import, either when requested to do so or in the event that HMRC suspect that goods may be being imported which are in breach of REACH. HMRC can also share intelligence with, and assist criminal investigations by, the named enforcing authorities.”⁴⁹

Exactly what role customs bodies should have in relation to REACH is not clear (indeed, HMRC’s own website barely even mentions REACH, never mind any discussion on their role in REACH enforcement). In February 2009, it was reported that a shipment of chemicals from a company in the US was blocked from entering a port in Belgium as customs officials demanded evidence of

⁴⁶ For current lists, see: <<http://www.direct.gov.uk/en/D11/Directories/Localcouncils/index.htm>> accessed 10 August 2014

⁴⁷ For an overview, see: Richard Macrory, *Regulation, Enforcement and Governance in Environmental Law* (Hart 2009)

⁴⁸ Forum (n 44) 4

⁴⁹ See: <<http://www.hse.gov.uk/reach/enforcement.htm>> accessed 10 August 2014

REACH pre-registration before entry.⁵⁰ While the chemicals contained in the ship may (or may not) have been subject to pre-registration or registration, nowhere in REACH is there an obligation on a manufacturer, importer or Only Representative (or anyone else) to provide evidence of such. This notwithstanding, Regulation 9(2) of the Enforcement Regulations grants the power to an officer of HMRC to, “detain, for not more than two working days, an article or substance which has been imported”. The grounds on which such detention may occur (for example, reasonable suspicion of non-compliance with a provision of REACH) are not set out in Regulation 9 and, thus, this may become an area of contention in the future between HMRC and importers. This ability to detain goods sits somewhat disjointedly with the comment by the Government, in the first REACH enforcement consultation paper, that, “It is not proposed to give HMRC a day to day inspection role for chemicals.”⁵¹ Exactly how and when goods have been, or will be, detained by HMRC under Regulation 9(2) is not known.

The above describes what we may call the ‘formal’ REACH enforcement regulators. In addition, the Government sees a number of more ‘informal’ individuals and bodies having a role to play:

“Enforcement will be risk based but will have a significant intelligence led component... A significant amount is likely to come from ‘whistle blowing’... Other groups such as environmental NGOs may also be monitoring the behaviour of companies they suspect of not complying with REACH.”⁵²

While the US has greater experience of NGOs as whistle blowers, watchdogs and private attorneys general, this is much more limited in the UK.⁵³

The Enforcement Regulations in Detail

Under the Enforcement Regulations, the primary obligation is on enforcing authorities to enforce the “listed REACH provisions” for which they are

⁵⁰ See: <<http://chemicalwatch.com/1851>> accessed 10 August 2014

⁵¹ DEFRA (n 42) 20

⁵² DEFRA (n 42) 18

⁵³ Susan Dagget, ‘NGOs as Lawmakers, Whistle Blowers, Watchdogs and Private Attorneys General’ (2002) 13(1) *Colorado Journal of International Environmental Law and Policy* 99

responsible.⁵⁴ Schedule 1 to the Enforcement Regulations contains the “listed REACH provisions”. What these do is reference a provision of REACH and the corresponding regulator with responsibility for enforcement in four areas of the UK: England & Wales; Scotland; Northern Ireland; and in respect of Offshore Installations. So, for example, the enforcement of Article 5 of REACH (which, as the reader will recall from Chapter 3, prohibits placing chemicals on the market which are subject to REACH without prior registration) is undertaken in England & Wales by the HSE, in Scotland by the HSE, in Northern Ireland by HSENI and for offshore installations by the HSE and HSENI. For the majority of “listed REACH provisions”, the HSE is the sole regulator. However, certain matters in the same jurisdiction are the potential remit of two or three or four separate regulators. So, for example, someone manufacturing a substance subject to a REACH Restriction (as discussed in Chapters 3 and 7) in one of the unoccupied seminar rooms at Cardiff University (a breach of Article 67(1) of REACH) may well find themselves subject to investigation by the HSE, the EA and Cardiff Council (the latter acting in two capacities as responsible regulator for: (i) consumer safety; and (ii) health and safety).⁵⁵

It is worth noting that the “listed REACH provisions” are not exhaustive in the sense that they do not correspond to every obligation or requirement contained within the text of REACH. Only those provisions of REACH which the Government consider “appropriate to enforce in the UK to make REACH work” have been included.⁵⁶ For example, certain of those matters set out in REACH which concern interaction with ECHA have been left out. In this context, the Government gave the following example:

“[ECHA] will be responsible for issuing registrations...and if an applicant fails to comply with the requirements of applications for registration, the Agency may simply reject the application.”

Although (as noted above), it is in no way clear exactly what responsibility ECHA has for REACH enforcement, this is not particularly contentious. However, certain

⁵⁴ Regulation 3(1) Hereafter, references to “Regulations”, “Parts” and “Schedules” are, save where explicitly stated otherwise, references to “Regulations”, “Parts” and “Schedules” contained within the Enforcement Regulations.

⁵⁵ Schedule 1

⁵⁶ DEFRA (n 43) 16

other REACH obligations have also not flowed down to become “listed REACH provisions”. Obligations in REACH to form a SIEF and to “make every effort” to reach agreement on matters relating to data generation cost sharing are not included as “listed REACH provisions”.⁵⁷ The reason given for this by DEFRA was that, “it would be impractical and inappropriate to resolve [such provisions] using criminal sanctions as they are matters for the civil law to resolve as and when appropriate.”⁵⁸ This may be somewhat disappointing for those subject to REACH who may have neither the inclination, time or other resources to turn to the civil law for the resolution of REACH related disputes. The time factor is especially important as the text of REACH does not allow for late registration due to a delay caused by civil law proceedings in a Member State (or indeed, for any other reason). The other block of matters contained within REACH but not a “listed REACH provision” under the Enforcement Regulations relate to the use of animals in the generation of chemical testing data. As was set out in Chapter 3, REACH aims to reduce the number of animals used for testing purposes.⁵⁹ However, the Enforcement Regulations make no reference to the animal testing provisions of REACH as the Government is of the view that existing legislation and associated licensing regime (contained, as referenced above, in the Animals (Scientific Procedures) Act 1986) are sufficient.

Enforcing authorities are mandated, under Regulation 4, to co-operate with each other, with ECHA and with REACH competent authorities in their own Member States and elsewhere “where [such co-operation] will facilitate compliance with, or the effective enforcement of, REACH in the European Union.” Exactly what would happen to an enforcing authority where such co-operation did not occur is not clear. At the same time, that whole notion of ‘co-operation’ is not defined. Regulation 4(2) does place an obligation on an enforcing authority to disclose information (to other national enforcers, ECHA and competent authorities) in certain circumstances, but, apart from this, no other explicit tasks of co-operation are enumerated.

⁵⁷ Articles 29 and 30, REACH

⁵⁸ DEFRA, ‘REACH Enforcement in the UK’ (February 2009) 5 - This document is now archived, but can be found here:

<<http://webarchive.nationalarchives.gov.uk/20130123162956/http://www.defra.gov.uk/environment/quality/chemicals/reach/documents/reach-enforcement-guidance.pdf>> accessed 10 August 2014

⁵⁹ Articles 13(1), 25(1) and 26(3), REACH

Given the large number of regulators enforcing REACH in the UK and the potential for overlap in their remit and function (both, as noted above), the Enforcement Regulations provide for so-called “enforcement agreements.”⁶⁰ While such are not obligatory, one enforcing authority may make an agreement with another enforcing authority to divide or allocate certain duties between them which they have in relation to the “listed REACH provisions.”⁶¹ This, in theory, should lead to an element of clarity as between regulators with overlapping functions and administrative convenience in the allocation of REACH enforcement obligations. The HSE comments that with these agreements, “...there is flexibility for the most appropriate enforcing authority to carry out enforcement in any particular case.”⁶² However, the fact that the “enforcement agreements” are not compulsory means that there could well be disparities across the UK (with some regulators entering into agreements and others choosing not to, for whatever reason). It is understood that, by the second half of 2013, no enforcement agreements had been entered into. In private correspondence with the author, the HSE commented that,

“This is because in the vast majority of our cases there has been only a single enforcing body responsible for the enforcement of the specific duty under consideration. Occasionally, for example where a number of points of a supply chain have been out of compliance, (where HSE would be responsible for trade to trade supply and Local Authorities responsible for retail sale) it has been agreed informally that a single body, normally HSE, will take the necessary action at the top of the chain.”⁶³

Parts 2 and 3 of Schedule 3 to the Enforcement Regulations could be considered a form of statutory enforcement agreement, in the sense that they set out whether the HSE or the health and safety team of a local authority has the obligation to enforce where there is a joint enforcement obligation. Such allocation of responsibility is said to flow from existing responsibilities on those bodies under pre-REACH health and safety law in the UK. If, for example, the HSE had prior responsibility for health and safety inspections at a given business, they tend to gain

⁶⁰ Regulation 5

⁶¹ Regulations 5(2) and 5(3)

⁶² See: <<http://www.hse.gov.uk/reach/enforcement.htm>> accessed 10 August 2014

⁶³ Copy on file with the author

responsibility for REACH enforcement for that business under Parts 2 and 3 of Schedule 3, even where a local authority may, under Schedule 1, have co-responsibility. As with other areas of the Enforcement Regulations, Parts 2 and 3 of Schedule 3 attempt to retain the status quo.

In the context of inter-agency co-ordination, there is also a Memorandum of Understanding which, it is understood, sets out agreement between the various REACH enforcement bodies in the UK on matters such as co-operation, information exchange and business compliance. However, this Memorandum has not been made public. The document was drawn up by the UK REACH Enforcement Liaison Group which, as the name suggests, contains members from the various REACH regulators and meets twice a year to discuss, among other matters, “grey areas” of emerging enforcement issues.⁶⁴ The minutes of the meetings of this group are publicly available online via the HSE website.⁶⁵

Interestingly, in the first consultation on REACH enforcement in the UK, the Government was keen to stress the lack of any substantial increase in regulatory burden for UK business flowing from the introduction of the Enforcement Regulations. They commented:

“[The REACH enforcement regulators] already enforce similar matters with existing legislation and in so doing visit premises and request information. So far as possible, the enforcement of REACH will be carried out in conjunction with these other matters and therefore it is not intended that businesses will see any more site visits than they currently experience nor visits from different regulators than those they deal with now.”⁶⁶

As is evident in the detail of the Enforcement Regulations, discussed below, there appeared to be a strong desire on the part of the Government to retain the status quo.

⁶⁴ See: <http://www.hse.gov.uk/reach/ukliaison.htm#a3>> accessed 10 August 2014

⁶⁵ *ibid*

⁶⁶ DEFRA (n 42) 9

Enforcement Powers

The powers of the various REACH regulatory agencies are set out in Schedule 6 of the Enforcement Regulations. The stated intention in the drafting of Schedule 6 was to give the regulators powers which were as close as possible to their existing enforcement powers in other areas.⁶⁷ Broadly, the powers relate to the entry of premises, the seizure of assets, the collection of information and samples and the service of various forms of notice. Schedule 6 is in four parts: Part 1 contains the powers for the environmental regulators (the EA, the SEA etc); Part 2 the enforcement powers for the health and safety regulators (HSE and local authorities); Part 3 the powers for trading standards (local authority consumer safety); and Part 4 for the Secretary of State. In setting out the enforcement powers for the four groups set out above, Schedule 6 highlights certain generic differences given to different regulators as regards the specific breadth and depth of their suite of enforcement powers. So, for example, while the Environment Agency is permitted to use force, where necessary in an emergency, to enter premises, the HSE is not.⁶⁸ The EA must give seven days' notice where entering residential premises.⁶⁹ No such obligation rests on the HSE.

Where and how the enforcement powers set out above would or could be exercised is not clear. For example, while the HSE has a dedicated REACH enforcement team, it is not known how local authorities are responding to their increased enforcement workload, how they are training their existing health and safety and consumer safety inspection teams, whether they have been given increased funding which corresponds to their increased enforcement role etc. While the enforcing authorities are placed under a duty to enforce,⁷⁰ how this duty is exercised remains a matter for their own discretion. As the Government put it, the Enforcement Regulations, "...do not specify any particular level of activity for the enforcing authorities and this will depend on their enforcement programmes and

⁶⁷ See both consultations on REACH enforcement in the UK, referenced above: DEFRA (n 42 and 43).

⁶⁸ Compare paragraph 1(a) of Part 1 of Schedule 6 with paragraph 1(a) of Part 2 of Schedule 6.

⁶⁹ Paragraph 2(a) of Part 1 of Schedule 6.

⁷⁰ Regulation 3(1)

resources.”⁷¹ In this content, several concerns relating to the ability of the REACH enforcement regulators to exercise their enforcement powers (including regulator resources) were set out in the responses to the Government’s first consultation on REACH enforcement.⁷² Detailed empirical research would be needed to understand whether these concerns have, as a matter of fact, materialised. There is no associated guidance to accompany the Enforcement Regulations, either by the Government (and on the DEFRA website) or by the HSE.

Penalties For Non-Compliance

While there are a variety of possible offences under the Enforcement Regulations, the penalties for non-compliance are the same. Any person found guilty of an offence is liable: (a) on summary conviction, to a fine not exceeding the statutory maximum (currently £5,000) or to imprisonment not exceeding three months, or both; or (b) on conviction on indictment, to an unlimited fine or to imprisonment not exceeding two years, or both. In the UK the breach of REACH, via the Enforcement Regulations, is a criminal offence. While this is common for many breaches of environmental law in the UK, the same cannot be said for the majority of other Member States in the EU. The nature of the penalties for breach of REACH under the Enforcement Regulations are similar to those for breaches of other areas of environmental law in the UK. This continues the theme with REACH enforcement in the UK of mapping the Enforcement Regulations onto an existing enforcement structure (i.e. no new regulator; no new penalties; and no new powers of enforcement). The reader will recall that the introduction to this Chapter set out that Article 126 of REACH required Member States to introduce national enforcement regimes which contained penalties for breach that are “effective, proportionate and dissuasive”. Interestingly, in the responses to the Government’s first consultation on REACH enforcement in the UK, half of those who responded thought that the above penalties were “effective, proportionate and dissuasive”; the other half did not.⁷³

⁷¹ DEFRA (n 43) 18

⁷² DEFRA (n 42)

⁷³ DEFRA (n 42) para 71

The primary offence under the Enforcement Regulations is for a person “to contravene a listed REACH provision or cause or permit another person to do so.”⁷⁴ There are, in addition, other offences set out in Regulation 13, including obstructing the enforcing authorities and providing false or misleading information. The idea that permitting a breach of a listed REACH provision amounts to an offence under the Enforcement Regulations is worthy of some reflection. The offence of permitting another to breach a provision of law is seen elsewhere in UK environmental legislation,⁷⁵ and usually connotes some power on the part of the ‘permitter’ to prevent or remedy the breach.⁷⁶ Exactly how this would play out in relation to breaches of “listed REACH provisions” under the Enforcement Regulations is not clear. Could, for example, the parent company of a wholly owned subsidiary be liable for failure by that subsidiary to comply with its obligations under REACH?

The only widespread defence under the Enforcement Regulations is to provide a “defence exemption certificate” made by the Secretary of State.⁷⁷ It is likely (although such is not stated) that this provision flows from the power contained in REACH for Member States to nominate certain substances as being exempt from the Regulation where it is necessary to exempt such substances in the interests of defence.⁷⁸ The exemption under REACH is an exemption for a given substance. The “defence exemption certificate” under the Enforcement Regulations, however, occurs where the Secretary of State decides that “it is necessary in the interests of defence for *a person to be exempt* from compliance with a listed REACH provision”.⁷⁹ Quite how an exemption for a given person from compliance with a listed REACH provision may be derived from the text of REACH is unclear. While it makes much greater practical sense for exemptions to be given to persons subject to REACH (who may manufacture or import substances which are used for

⁷⁴ Regulation 11(1)

⁷⁵ For example, under s85 of the Water Resources Act 1991 and Part 2A of the Environmental Protection Act 1990.

⁷⁶ See, for a review in the context of contaminated land, Robert G Lee and Daniel Lawrence, ‘Permitting Uncertainty: Owners, Occupiers and Responsibility for Remediation’ (2003) 66(2) MLR 261

⁷⁷ Regulation 7(a). The particulars of the contents and form of the certificate are set out in Schedule 4 of the Enforcement Regulations.

⁷⁸ Article 2(3), REACH.

⁷⁹ Paragraph 1, Schedule 4. Own emphasis added.

defence purposes) especially where such substances may be used, in addition, in a variety of non-defence related applications, this is not what the text of REACH says. This then raises an interesting question about transposition.

In addition to the defence of having a “defence exemption certificate”, a person may plead “reasonable excuse” where charged with an offence of failure to comply, in various forms, with a regulator.⁸⁰ There is also a defence of lawful disclosure in relation to the provision of certain information received from HMRC.⁸¹ However, aside from these three, there are no other statutory defences in relation to the Enforcement Regulation offences. This being said, the HSE comments that, “...enforcing authorities will usually take into account the efforts made by companies to comply when deciding what kind of enforcement action to take.”⁸²

As is common with modern environmental legislation, directors of companies (and certain other company ‘officers) may be liable as well as the body corporate where an offence is committed with their consent or connivance or can be attributed to their neglect.⁸³ In addition, Regulation 20 provides that if an enforcing authority is of the opinion that proceedings against a person (natural or legal) for an offence would afford an ineffectual remedy against that person, the enforcing authority may take civil proceedings against that person for the purpose of seeking such remedy as the enforcing authority believes is appropriate in the circumstances. To date, no civil proceedings have been instituted.⁸⁴

Enforcement Activity to Date

While the above has described the range of formal powers open to the REACH enforcement regulators in the UK and the associated penalties for breaches of any “listed REACH provision”, it was expected that a less formal approach would

⁸⁰ Regulation 13(3)

⁸¹ Regulation 13(7)

⁸² See: <<http://www.hse.gov.uk/reach/enforcement.htm>> accessed 10 August 2014

⁸³ Regulation 15(1). The seminal case in this area, and the best starting point, is: *Woodhouse v. Walsall Metropolitan Borough Council* [1994] Env LR 3

⁸⁴ Private email from the HSE of 27 September 2013, on file with the author.

initially be taken. In their first consultation paper on REACH enforcement in the UK, the Government commented that,

“Initial enforcement action may be to advise businesses of their obligations and encourage compliance, followed if necessary by the use of enforcement notices. Prosecution would only be used as a last resort.”⁸⁵

To date, 57 improvement notices have been served by the HSE in respect of breaches of the Enforcement Regulations but there have, as yet, been no prosecutions.⁸⁶ This is despite the hundreds of REACH related inspections conducted by the HSE as part of the REACH-EN-FORCE projects discussed above. As regards enforcement by the other REACH regulators, the HSE have commented that they, “are aware of two separate local authority prosecutions brought by their trading standards departments, concerning restricted substances being supplied to consumers.”⁸⁷

Conclusions

What we see with the enforcement of REACH in the UK is layer upon layer of EU and national regulatory agencies and other bodies (such as the Forum) with varying (and at times overlapping) degrees of responsibility for the enforcement of REACH and mandates to co-operate and co-ordinate. At the EU level, the Commission, ECHA and the Forum each have roles to play. In the UK, over four hundred separate environmental, health & safety and consumer safety bodies at national and local levels make up the corpus of REACH enforcers. The reality, however, may well be that the only ‘real’ regulator in the UK is the HSE. Evidence to date suggests little enforcement activity in particular on the part of local authorities. The degrees of overlap (between the UK regulators *inter se* and between those regulators, ECHA and the Forum) and the allocation of enforcement responsibility for certain matters are, at times, less than clear. It is also in no way certain that any effective harmonisation of REACH enforcement across the EU will be achieved.

⁸⁵ DEFRA (n 42) 14

⁸⁶ See: <<http://www.hse.gov.uk/notices/>> accessed 10 August 2014

⁸⁷ Private email from the HSE of 27 September 2013. Copy on file with the author.

What is striking in this area is the lack of guidance. ECHA says almost nothing about enforcement, the Forum promises guidance but little has appeared to date and while the HSE provides ‘Bitesize Advice’ and highlights case studies, such go to compliance with REACH and there is no guidance whatsoever on the Enforcement Regulations. Even where the HSE does offer advice on REACH compliance, it primarily directs those with responsibilities under REACH back to ECHA and the ECHA guidance.⁸⁸ As regards guidance on enforcement produced by ECHA’s Enforcement Forum, this Chapter has highlighted single instances of each of the amplification, standardisation and translation functions reviewed in earlier Chapters. In terms of amplification, the guidance by the Enforcement Forum on complaints handling under Article 33(2) is striking in that it offers advice, but specifically states that there is no need for a “specific route” of complaints handling to be set out. While registrants operating in multiple EU jurisdictions might have hoped for greater standardisation of enforcement legislation and enforcement practices, such does not exist. The sole exception is seen in the “Strategies for Enforcement” paper by the Enforcement Forum which sets out to achieve harmonisation of enforcement frameworks (but at only a very superficial level). In terms of translation, the text of REACH is clear that there is no hierarchy among the tasks for which ECHA’s Enforcement Forum is responsible. However, the Work Programme of the Forum is clear in prioritising various tasks over others.

This Chapter and the three preceding Chapters of this thesis have set out, in some considerable depth, the key elements of REACH: the creation of data; the registration of that data with ECHA; data evaluation; chemical bans; and the enforcement of the Regulation. For each element, the accompanying guidance has also been reviewed and critique offered up on what function(s) such guidance serves. The following Chapter explores how this thesis contributes to, and challenges, new governance scholarship. It also sets out, in detail, the differentiation that can be seen in soft law, highlighted through the documentary analyses in Chapters 5-8.

⁸⁸ See: <<http://www.hse.gov.uk/reach/resources.htm>> accessed 10 August 2014

CHAPTER 9

PLAYING HARD AND SOFT WITH LAW: REACH, NEW GOVERNANCE AND HYBRIDITY

This thesis provides an exploratory, explanatory and normative account of modern EU chemicals regulation. It contributes to scholarship on new governance, particularly the subset of literature concerned with hard and soft law, in two key ways: (a) it provides detailed, thick, granular empirical data on hard and soft EU chemicals regulation, at a level previously unseen; and (b) it offers a rich case study on hybridity (for these purposes, the yoking of soft norms onto hard). As such, it gives a nuanced, robust, differentiated account of EU governance and amounts to the “careful delineation of variables and substantial empirical work” called for by Trubek and Trubek in this area.¹ This thesis is the first account of REACH to fully explore relationships between the Regulation and its post legislative guidance, and how the latter interacts with the former. Guidance is not mentioned in the index to Drohmann and Townsend’s edited collection on REACH.² It is discussed in under two pages in Bergkamp’s practitioner text,³ and, by her own admission, Korkea-aho opens only a “small window” into this area.⁴

The remainder of this Chapter unfolds as follows. It begins by exploring in detail how this thesis contributes to new governance scholarship. It discusses how the work in this thesis challenges a number of assumptions in the new governance literature and how REACH is peculiar in a number of ways when compared with other new governance regimes. The Chapter then turns to consideration of how we can, using the data in this thesis, explore differentiation within soft law along a number of axes: authorship; formats; addresses; acceptance; functions; genesis; review; impact; and coverage.

¹ David M Trubek and Louise G Trubek, ‘The Co-Existence of New Governance and Legal Regulation: Complementarity or Rivalry?’ (Paper presented to Annual Meeting of the Research Committee on the Sociology of Law, Paris, July 2005) 8

² Dieter Drohmann and Matthew Townsend (eds), *REACH: Best Practice Guide to Regulation (EC) No 1907/2006* (Hart 2013)

³ Lucas Bergkamp (ed), *The European Union REACH Regulation for Chemicals: Law and Practice* (OUP 2013) sections 2.16-2.22

⁴ Emilia Korkea-aho, ‘Laws in Progress: Reconceptualizing Accountability Strategies in the Era of Framework Norms’ (2013) 2(2) *Transnational Environmental Law* 363, 369

Contributions of and to New Governance Scholarship

New governance approaches, in the EU and elsewhere, have emerged as policy makers respond to changes in society, the economy (financial and political) and to innovations in public administration. De Burca 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”; the second is the need to manage interdependence where divergent national regulatory regimes affect one another.⁵ 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).

Scholarship on ‘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, decentralised, experimental, multi-level, reflexive and participatory forms of ordering.⁶ Or, as Armstrong frames it, this scholarship 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.”⁷ As regards the latter, this thesis shows (discussed in detail below) how newer modes of governing, via post legislative soft norms, may simply be replicating that traditional world of hierarchy. 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.⁸ This thesis is another case study mapping project, but serves as justification for this approach and a challenge to those who avoid thick, granular work: it is the detailed mapping

⁵ Grainne de Burca, ‘New Governance and Experimentalism: An Introduction’ (2010) 2 *Wisconsin Law Review* 227, 232

⁶ Joanne Scott and David M. Trubek, ‘Mind the Gap: Law and New Approaches to Governance in the EU’ (2002) 8 *European Law Journal* 1, 16; Kenneth Armstrong and Claire Kilpatrick, ‘Law, governance, or new governance - the changing open method of coordination’ (2007) 13(3) *Columbia Journal of European Law* 649, 654

⁷ Kenneth A Armstrong, ‘New Governance and the European Union: An Empirical and Conceptual Critique’ in Grainne de Burca, Claire Kilpatrick and Joanne Scott (eds) *Critical Legal Perspective on Global Governance: Liber Amicorum David M Trubek* (Hart 2014) 251

⁸ Armstrong and Kilpatrick (n 6) 652

of the contours of the operationalization of REACH that have highlighted nuances in, and challenges to, current understandings of EU governance. As de Burca has noted, “if we are to understand [new governance] change, there is no substitute for careful and thorough research.”⁹

There has been a notable increase in the use of 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.¹⁰ Post legislative guidance in the EU is a form of soft law (discussed in detail in Chapter 2), in that it is a governance arrangement that operates alongside or is blended with EU ‘hard law’ that comes from the treaties, regulations and directives and the Community Method.¹¹ The work in this area splits primarily between those who observe this shift as an indicative development in the maturing EU legal landscape,¹² and those who raise objections (as regards transparency, accountability and competence creep) to its use.¹³ This thesis, 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: participation; accountability; transparency etc);¹⁴ and second, 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 and makes the claim that that order is legitimate more fragile (due to the issues of legitimacy just discussed). Much of the early work in the new governance field is on contrasts: on setting out and exploring the

⁹ Grainne de Burca, ‘Introduction’ (2007) 31(3) *Columbia Journal of European Law* 3

¹⁰ Joanne Scott, ‘In Legal Limbo: Post-Legislative Guidance as a Challenge for European Administrative Law’ (2011) 48 *Common Market Law Review* 329, 330

¹¹ David M Trubek, Patrick Cottrell and Mark Nance, ‘Soft Law, Hard Law and European Integration: Toward a Theory of Hybridity’ (University of Wisconsin Legal Studies Research Paper No. 1002, 2005) 1

¹² See the review here: Linda Senden and Ton van den Brink, ‘Checks and Balances of Soft EU Rule Making’ (Report for the European Parliament, March 2012) 15

¹³ 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

¹⁴ Scott and Trubek (n 6) 17

dichotomies between old and new governance, between hard and soft law. As such, new governance scholarship has been criticised for its ‘definition-by-contrast’ approach and for idealising the ‘new’ over the ‘old’.¹⁵ This is in spite of the origins of this body of 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.”¹⁶ More recent scholarship, however, suggests that such a binary distinction does not account for variations in policy development, implementation, assessment and justiciability of various instruments.¹⁷ 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.¹⁸ The exploration of REACH in this thesis suggests that a harder look at soft norms will help to show that the bright lines are not so bright. As Armstrong argues, and I would agree, differentiation in EU law is much more important as a site of study than scholarship that simply charts a shift from traditional towards newer forms of governance.¹⁹ 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.”²⁰

This thesis has focused 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. This is discussed in more depth below. This thesis moves the debate beyond the existing, somewhat blunt

¹⁵ On the former, see: Grainne de Burca and Joanne Scott, ‘Introduction’ in Grainne de Burca and Joanne Scott (eds) *Law and New Governance in the EU and US* (Hart 2006). On the latter, see: Armstrong (n 7)

¹⁶ Christian Joerges and Maria Weimer, ‘A Crisis of Executive Managerialism in the EU: No Alternative?’ in Grainne de Burca, Claire Kilpatrick and Joanne Scott (eds) *Critical Legal Perspective on Global Governance: Liber Amicorum David M Trubek* (Hart 2014)

¹⁷ Caroline de la Porte and Phillippe Pochet, ‘Why and how (still) study the Open Method of Co-ordination (OMC)?’ (2012) 22 *Journal of European Social Policy* 336, 339

¹⁸ Armstrong and Kilpatrick (n 6) 654

¹⁹ Armstrong (n 7) 252

²⁰ *ibid*

typologies of soft norms that have compared ‘preparatory and informative instruments’ and ‘interpretative and decisional instruments’;²¹ or “soft regulatory rule-making” (involving para-law policy-steering instruments) with “soft administrative rule-making” (involving post-legislative guidance instruments).²² The functions, formats and blends of post legislative norms offered up by this thesis are set out in detail below.

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.²³ 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”.²⁴ 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”.²⁵ While these notions of ‘yoking’ and ‘fusing’ are interesting, and intellectually neat, what we see in REACH (as discussed below) 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 Burca writes of “different approaches yoked together in a single and increasingly integrated framework.”²⁶ With REACH, and as set out below, what we have is perhaps not just an hybrid hard law/soft law approach, but an hybrid regime (hard and soft, public and private, foreseen and not foreseen, multiple, and imperfect) for chemicals control. It is worth noting here that earlier notions of ‘hybridity’, including those by Trubek and Trubek and also de Burca 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

²¹ Linda Senden, *Soft Law in European Community Law* (Hart 2004) 118

²² Senden and van den Brink (n 12) 12; Linda Senden, ‘Soft Post Legislative Rulemaking: A Time for More Stringent Control’ (2013) 19(1) *European Law Journal* 57, 60

²³ The full spectrum of possible configurations is set out in detail here: David M Trubek and Louise G Trubek, ‘New Governance and Legal Regulation: Complementarity, Rivalry and Transformation’, Wisconsin Law School Legal Studies Research Paper Series (Paper No 1047, May 2007)

²⁴ *ibid* 3 (emphasis as in the original)

²⁵ Trubek and Trubek (n 22) 5

²⁶ Grainne de Burca, ‘Europe: Race Discrimination Law’ in Grainne de Burca and Joanne Scott (eds) *Law and New Governance in the EU and the US* (Hart Publishing 2006) 119

in the same field to promote the same goals (without necessarily being fused, or “yoked”, together).²⁷ This thesis is concerned with the situation when soft norms are yoked with 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.²⁸ This is a significant gap in the field, given the increasing use of guidance in this way; a gap which this thesis seeks to part fill.

Trubek and Trubek set out a “functional typology” for hybrid (or ‘transformed’) law.²⁹ In some cases, laws aim at problem solving or conflict resolution through the creation of new governance procedures.³⁰ In other areas, law provides recourse to rights when new governance processes fail.³¹ Thirdly, new governance may allow actors to exceed minimum standards set down in law, which de Burca and Scott call “default hybridity”.³² 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.”³³ This approach, they argue, is seen in the Water Framework Directive, EU employment discrimination regulation and EU health and safety regulation.³⁴ REACH shows that this functional typology of hybridity may benefit from further work. To give one example (the others are set out in depth below), 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; while, at the

²⁷ Trubek and Trubek (n 1), Grainne de Burca and Joanne Scott, ‘Governance, Law and Constitutionalism’ in Grainne de Burca and Joanne Scott (eds) *Law and New Governance in the EU and the US* (Hart Publishing 2006)

²⁸ There are only a handful of other works that consider the role of post legislative guidance in particular regulatory contexts: see Scott (n 10); Senden (n 21); Joanne Scott and Jane Holder, ‘Law and New Environmental Governance in the European Union’ in Grainne de Burca and Joanne Scott (eds) *Law and New Governance in the EU and the US* (Hart Publishing 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

²⁹ Trubek and Trubek (n 22) 10-11

³⁰ They say this can be seen with the EU’s Environmental Impact Assessment Directive, citing Scott and Holder (n 26)

³¹ Here, Trubek and Trubek cite the example of the EU’s anti-race discrimination regulation.

³² De Burca and Scott (n 25)

³³ Trubek and Trubek (n 22) 11

³⁴ The WFD as a hybrid is discussed in Scott and Holder (n 26); 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)

same time, other actors (public and private), in ways not foreseen in the Regulation, have also contributed to the hybrid nature of REACH (industry, DCG, NGOs, MSCAs 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”.³⁵ 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 RIPs to the current multiple modes and forms of norm shaping, is complex.

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 phenomenon, rather than, as is seen in this thesis (and set out in detail below) differentiated, hierarchical, plural and worthy of close scrutiny. This thesis 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 addressed to Member States;³⁶ 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).³⁷ The thesis shows how guidance is more than “a useful interpretive tool”;³⁸ in the context of REACH, the guidance effectively operationalises (to greater or lesser degrees in different contexts) the entirety of the Regulation. This thesis, however, also reinforces some of the core ideas of new governance approaches as flexible, deliberative, diverse and experimental, each to lesser or greater degrees as regards different aspects of REACH (and discussed more fully below).

³⁵ Trubek and Trubek (n 1) 3

³⁶ ECHA, ‘Guidance on the Communication of Information on the Risks and Safe use of Chemicals’ (Version 1, December 2010). See: <http://echa.europa.eu/documents/10162/13639/risk_communications_en.pdf> accessed 10 August 2014

³⁷ ECHA, ‘Guidance on Data Sharing’ (Version 2.0, April 2012) – see: <http://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf> accessed 10 August 2014

³⁸ Scott (n 10) 351

For EU scholars, this thesis 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”.³⁹ Much like Lange’s work on EU pollution control, this thesis pushes our understanding of EU law in context.⁴⁰ Law is said to be both “the object and the agent” of European integration.⁴¹ Soft norms could, therefore, be seen as a challenge to the legitimacy that the EU has gained 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”.⁴² 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.”⁴³

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, one might 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 destabilising and disintegrative effects of new governance in the EU are arguably less significant with hybrids. This is discussed more in Chapter 10.

Having set the scene on new governance scholarship, and on how this thesis contributes to aspects of that field, the following section looks at how REACH is somewhat different to other EU regulatory regimes, and discusses what this means as regards certain assumptions about new governance forms and functions. The

³⁹ Senden (n 21) 57

⁴⁰ Bettina Lange, *Implementing EU Pollution Control: Law and Integration* (CUP 2008)

⁴¹ Renaud Dehousse and Joseph HH Weiler, ‘The Legal Dimension’ in William Wallace (ed) *The Dynamics of European Integration* (Pinter 1990) 243

⁴² David and Louise Trubek, ‘The World Turned Upside Down: Reflections on New Governance and The Transformation of Law’ (2010) *Wisconsin Law Review* 719, 724

⁴³ Mark Dawson, ‘Soft Law and the Rule of Law in the European Union: Revision or Redundancy’ (Robert Schuman Centre for Advanced Study Working Paper, No 2009/24, 2009) 8

Chapter then sets out the complex differentiation within soft law that this thesis has highlighted.

The Peculiarities of REACH

REACH is a Regulation. It is long. It is complex. It has a central, overseer EU agency, ECHA. It was born because of frustration with previous EU chemicals regulation. The guidance produced under REACH is, in many (if not all) places, highly specific and highly detailed. Each of these facts pushes at different assumptions in the new governance scholarship,⁴⁴ and at other new governance examples. Soft law is often seen as supplanting or supplementing traditional forms of regulation; however, REACH is not one of the ‘Model Directives’ in which the task of drawing up technical specifications is left to EU standardisation bodies.⁴⁵ Similarly, REACH looks quite different to the Water Framework Directive, where most of the existing work on post legislative norm elaboration exists.⁴⁶ Others have argued that REACH is an example of framework legislation,⁴⁷ which has been described as “laws in progress, providing little explicit guidance about the conduct of those they govern.”⁴⁸ This is both accurate and very misleading. REACH has many framework provisions (e.g. the bare command to form a SIEF); but the Regulation is also very prescriptive and detailed in other areas (e.g. in the technical content advice on registration dossiers). Contrast this with Scott, who argues that,

“post legislative guidance is deployed to elaborate upon the meaning and implications of framework norms; that is to say in precisely those circumstances in which the relevant EU norm may lack the degree of clarity and precision to confer direct effect.”⁴⁹

Scholars interested in the EU’s scheme for integrated pollution prevention and control have suggested there are “serious theoretical and empirical concerns

⁴⁴ As set out here: Trubek and Trubek (n 40) 721

⁴⁵ For a discussion of these, see: Harm Schepel, *The Constitution of Private Governance* (Hart Publishing 2005) 227ff

⁴⁶ Scott and Holder (n 26); Howarth (n 26)

⁴⁷ Christian Hey, Klaus Jacob and Axel Volkery, ‘Better Regulation by New Governance Hybrids? Governance Models and the Reform of European Chemicals Policy’ (2007) 15 *Journal of Cleaner Production* 1859; Korkea-aho (n 4) 363

⁴⁸ Korkea-aho (n 4) 364

⁴⁹ Scott (n 10) 346

regarding the applicability of soft regulation in heterogeneous regulatory regimes such as the EU.”⁵⁰ This, they argue, is because of the relative ‘softness’ of the soft regulation being deployed (i.e. lacking precision). The same simply cannot be said of REACH, where norms are formed through top down (as well as bottom up) processes (i.e. via mandate in the Regulation and through the orchestration of ECHA), and where many of the norms seen in ECHA’s guidance are precise, prescriptive and highly detailed.

Critics have attacked new governance approaches for the lack of clear hierarchical rules; there is some suggestion that command and control regulation may be needed to minimize the incentives for private gain.⁵¹ REACH, however, contains a number of very clear command and control provisions: for example, the ability for ECHA to refuse a registration dossier (which effectively removes a substance from the market); the power of the Commission to ban, in full or in part, any chemical. The vast majority of REACH guidance comes from ECHA. Contrast this with the Water Framework Directive (where post legislative guidance is the product of informal working groups); or the Emissions Trading Scheme (where guidance nominally comes from the Commission).⁵² At the same time, most of the case law in this area (discussed in Chapter 4) concerns soft norms issued by the Commission (and not an EU agency). REACH, therefore, might be more easily compared with modern EU food or financial regulation, which have strong, centralising EU agencies.⁵³ However, and unlike these two spheres,⁵⁴ REACH was not a new governance approach born of a widespread crisis or series of crises. The role of ECHA means that comparing REACH and its guidance to other EU environmental spheres is only partly instructive. For example, guidance produced in the form of BREFS under IPPC has been questioned due to a lack of capacity in

⁵⁰ Charampos Koutalakis, Aron Buzogany and Tanja A Borzel, ‘When soft regulation is not enough: The integrated pollution prevention and control directive of the European Union’ (2010) 4 *Regulation & Governance* 329, 340

⁵¹ Robert B Ahdieh, "The Visible Hand: Coordination Functions of the Regulatory State," (2010) 95 *Minnesota Law Review* 578

⁵² Scott (n 10)

⁵³ Ellen Vos, ‘Responding to Catastrophe: Towards a New Architecture for EU Food Safety Regulation?’ in Sabel and Zeitlin (eds), *Experimentalist Governance in the European Union* (OUP 2010) ; Terry Marsden, Robert Lee, Andrew Flynn and Samartha Thankappan, *The New Regulation and Governance of Food: Beyond the Food Crisis?* (2 Aug 2012); Julia Black 'Paradoxes and Failures: -New Governance- Techniques and the Financial Crisis' (2012) 75 (6) *Modern Law Review* 1037

⁵⁴ de Burca (n 5)233

various EU member states to enforce the regime.⁵⁵ While the enforcement of REACH is a matter for individual Member States, ECHA, as the core regulator, is the single point of decision making in a number of core areas (such as the acceptance or rejection of registration dossiers).

What, then, does the above mean? Is the control of chemicals special in that it requires both a very large, very complex, often detailed Regulation with a new EU agency, together with a wealth of even more detailed/complex/specific/lengthy guidance? Chemicals are a private, more than a public good (though there is obviously a public interest in chemicals, chemical risks and the chemicals market); they are a source of primarily private and not public exploitation; they are complex and an area which is heavily reliant on various forms of expertise; they are also an area in which there is rapid, continual and widespread innovation in application and development. There is no real direct public consumption of chemicals. The EU chemicals market is vast and previous regulatory regimes for chemicals control have failed. However, none of these factors really tell us *why* REACH is a Regulation and *why* it has been elaborated, and operationalised, via post legislative guidance in the way that it has. As a consequence, REACH is a fascinating site of study: it is both very ‘new governance’ (multiple modes of regulation; multiple forms of norm; multiple actors); and a challenge to a number of new governance assumptions. In many ways, it is the size of REACH and its guidance that allows for a fuller account than has been previously seen of the very different and complex interactions between hard and soft law. It is not so much that conclusions drawn about hybridity in other work are wrong, but that the nature of their case studies (i.e. their data) have not perhaps allowed sufficient space for the nuanced meanings seen in this thesis. These nuances, and the fuller account of post legislative normative shaping, are set out further in the section that follows.

Differentiation Within Soft Law

The term ‘hybrid’ is used in a number of contexts in the two schools of regulation and governance. For regulation scholars, a hybrid is seen where regulation is

⁵⁵ Koutalakis et al (n 48)

multi-modal and/or where public and private forms of regulation co-exist;⁵⁶ for governance scholars, a hybrid occurs where hard and soft law complement each other, occupying the same field to promote the same goals. REACH is hybrid in both of these senses. However, the detailed review of the Regulation offered up in this thesis suggests that ‘hybrid’ is an umbrella term for what is seen in practice as regards the governance of the EU’s flagship chemicals regime. As Borzel has argued, “The EU’s governance architecture is too multifaceted to be captured by one particular mode.”⁵⁷ With REACH, and the guidance that shapes its operation, this thesis has highlighted a differentiation within soft law along a number of axes: authorship; formats; addresses; acceptance; functions; genesis; review; impact; and coverage. As such, this thesis offers up a rich and nuanced vision of hybridity in modern EU governance and drives towards the “functional theory of hybrids” that Trubek and Trubek called for almost a decade ago (and which has not been much advanced in that period).⁵⁸ Chart 9.1 at the end of this chapter sets out this differentiation in pictorial form, and the following sections look in depth at each of the ways in which the post legislative guidance that frames the operation of REACH can be differentiated.

1. Authorship

The guidance that shapes the operation of REACH comes not only from the regulator created to oversee the Regulation, ECHA, but also from a variety of other sources, public and non-public. At the same time, while ECHA is the official author of its own guidance, this obscures the actors who may have contributed to the policy or drafting of the text.⁵⁹ Thus, REACH is both a governance hybrid in the yoking of hard and soft law, but also in the welding of public and private spheres of influence in the context of guidance development and authorship. This provides an

⁵⁶ David Levi-Faur, ‘Regulation and Regulatory Governance’ (Jerusalem Papers in Regulation & Governance - Working Paper No. 1, February 2010)

⁵⁷ Tanja A. Borzel, ‘Experimentalist New Governance in the EU: The Emperor’s New Clothes?’ (2012) 6 Regulation & Governance 378, 380

⁵⁸ David M Trubek and Louise G Trubek, ‘Hard and Soft Law in the Construction of Social Europe: The Role of the Open Method of Co-Ordination’ (2005) 11 European Law Journal 343, 364

⁵⁹ The same was seen in Lange’s empirical study of BREFs under the IPPC Directive: Lange (n 38) 120

example of multi-level governance within the tier of post legislative norm elaboration.⁶⁰ As such, this thesis confirms the “horizontal spread of EU governance to new institutional structures like agencies or committees or networks.”⁶¹ The use of private norms in public settings, what Schepel calls ‘private regulators in law’, is seen in other contexts.⁶² But, with REACH, the role of the private actors is something more than just standard setting; these actors, and their norms, are a significant part of the operationalization of the Regulation. As such, REACH is a good example of a form of experimentalist governance which, “builds on our capacity for learning from other’s experience and for multi-layered problem-solving in and across various formal and informal networks and ‘publics’.”⁶³

As is shown in Chart 9.1, and discussed in Chapter 4 in more depth, ECHA, Member States, industry groups, NGOs and the somewhat obscure Directors Contact Group (‘DCG’) all issue guidance shaping the operation of REACH. In their review of EU multilevel regulation, Chowdhury and Wessel comment that,

“The regulatory space may or may not be reflected in the formal legal/regulatory framework that governs the sector. In other words, the regulatory space may be populated with actors that do not have formal legal roles but play a critical role in the regulatory process.”⁶⁴

This is certainly true in the context of REACH. As noted earlier, the guidance produced under REACH was both planned and not planned; certainly, there is nothing in the Regulation to suggest that such a wealth of

⁶⁰ Levi Faur (n 54) 15

⁶¹ Kenneth A Armstrong, ‘The Character of EU Law and Governance: From “Community Method” to New Modes of Governance’ (2011) 64 *Current Legal Problems* 179, 183

⁶² Harm Schepel, ‘Private Regulators in Law’ in Joost Pauwelyn, Ramses Wessel, and Jan Wouters (eds) *Informal International Lawmaking* (OUP 2012) 356

⁶³ Michael Wilkinson, ‘Three Conceptions of Law: Towards a Jurisprudence of Democratic Experimentalism’, (2010) *Wisconsin Law Review* 673, 676

⁶⁴ Nupur Chowdhury and Ramses A. Wessel, ‘Conceptualising Multilevel Regulation in the EU: A Legal Translation of Multilevel Governance’ (2012) 18(3) *European Law Journal* 335, 339. Although it is not entirely clear whether Chowdhury and Wessel’s vision of “multilevel regulation” would apply to post legislative guidance issued by private actors – for them, to be within multilevel regulation, the relevant acts and/or activities must “directly or indirectly have a legal effect” (*ibid*, 357).

actors, private and public, would be involved in REACH's post legislative norm setting. As such, the authorship of guidance that elaborates REACH, and helps to operationalise the regulation, may be an example of the "polyarchic distribution of power" described by Sabel and Zeitlin.⁶⁵ What we see with REACH is that the deliberative, epistemic communities involved in the creation and promulgation of ECHA guidance are public and private, national and supranational.

Armstrong writes that what is seen over time in the EU is a, "relocation of norm production and norm elaboration to a range of institutional locations outside of, but not unconnected to, the inter-institutional decision making processes associated with the Community Method."⁶⁶ The involvement of private actors is a recurring theme in new governance work.⁶⁷ However, it is not entirely clear whether the notion of hybridity put forward by Trubek and Trubek allows for yoked soft norms originating from beyond the state. One might argue that this type of yoking is simply not possible, in that such private sector guidance/shaping is simply not 'law'. While this may be true, there is nothing to suggest that the guidance issued by the DCG, and other private actors (including, in particular, Cefic), does not have practical effects and/or does not shape the behaviours of those subject to the Regulation. On a functional level, the actions and behaviours of those subject to REACH are shaped by norms public and private, hard and soft. Here, then, we may see yoking between two very different forms of soft instrument; guidance issued by public actors; and guidance issued by private actors, both yoked to the same underlying hard law norm.⁶⁸ This thesis thus shows other ways of how notions of regulatory capitalism,⁶⁹ and public/private regulatory hybrids, can and should contribute to

⁶⁵ Charles Sabel and Jonathan Zeitlin, 'Learning from Difference: The New Architecture of Experimentalist Governance' in Charles Sabel and Jonathan Zeitlin (eds), *Experimentalist Governance in the European Union* (OUP 2010) 9

⁶⁶ Armstrong (n 7) 252

⁶⁷ Armstrong and Kilpatrick (n 6) 652

⁶⁸ Armstrong has raised this as a form of hybrid in the context of Europe 2020 and 'yoking' across different policy areas. See: Kenneth Armstrong, "EU Social Policy and the Governance Architecture of Europe 2020" [2012] 18(3) *Transfer: European Review of Labour and Research* 285, 297

⁶⁹ For an overview, see: David Levi Faur, 'The Global Diffusion of Regulatory Capitalism' (2005) 598 *Annals of the American Academy of Political and Social Science* 12

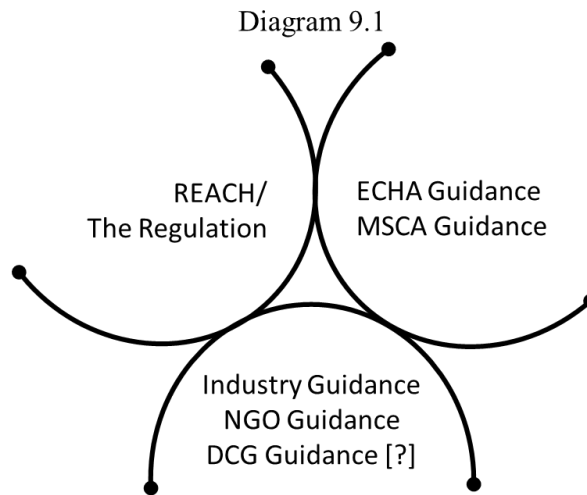
understandings of new governance. There is no “neat and tidy regulatory space” with REACH.⁷⁰ Instead, the space is filled with multiple actors on multiple levels; forming multiple hybrids in the same regulatory space. This is another example of how, “social steering is becoming more and more of a property of the interaction of organisations, networks and associations involving both public and private actors.”⁷¹

There is no clear line, with the post legislative shaping of REACH, as to when the guidance will be authored by private parties and when it will be issued by ECHA, MSCAs or other public bodies. It is not as if the highly technical, highly expert guidance is produced solely by the private sector (who are often said to be the holders of such expertise); indeed, this thesis has shown that much of ECHA’s own guidance is dense and technical. In this regard, this thesis presents a challenge to Schepel’s argument, in the context of EU approaches to standardisation, that expertise and social complexity force regulators, “to draw on private actors, to bargain with organised private actors, and even to rely completely on private parties’ judgments.”⁷² What we see are areas in which REACH guidance issued by public actors overlaps with that produced by private actors (e.g. SIEF formation and organisation); areas in which guidance issued by public actors goes to some aspect of REACH, but is not also within the sphere of guidance by private actors (e.g. risk communication by Member States); and areas in which guidance produced by private actors has no mirror in that produced by public actors (e.g. DCG advice on registration obligations when groups of companies are sold, or sub-divided). This is represented by Diagram 9.1 below.

⁷⁰ Mark Thatcher and David Coen, ‘Reshaping European Regulatory Space: An Evolutionary Analysis’ (2008) 31(4) *West European Politics* 806, 809

⁷¹ Schepel (n 43) 19

⁷² Schepel (n 43) 409



The preceding discussion has centred on guidance produced other than by ECHA. As for ECHA’s own guidance, the 2011 Consultation Procedure on Guidance details that the Secretariat decides who to consult and on the time frames given for consultation.⁷³ There is then no set body of contributors to, or authors of, ECHA’s own guidance. Much of the consultation is ‘closed’ in that it involves experts “whose nominations have been received by a specified deadline”⁷⁴ and who are then formed into Partner Expert Groups (‘PEGs’).⁷⁵ The ECHA website does not detail lists of experts within PEGs formed as part of previous consultations on guidance. This is a striking omission in transparency and the reason for the lack of disclosure is not clear. Only in limited situations (for example, for entirely new guidance) will ECHA engage in full public consultation. Even where full public consultation does take place, the Agency works particularly closely with what it terms “Accredited Stakeholder Organisations” (‘ASOs’), who represent differing fields of competence at the EU level. It will be recalled, from Chapter 4, that the vast majority of ASOs are industry representative bodies: only 7 out of the 69 accredited ASOs represent civil society.⁷⁶ Others have suggested that the success of new governance approaches is, “significantly affected by the extent to

⁷³ ECHA, ‘(Revised) Consultation Procedure on Guidance’ (MB/14/2011 final, 2011)

⁷⁴ It is not clear what this deadline is or how it is disseminated.

⁷⁵ ECHA (n 71) 5

⁷⁶ See: <<http://echa.europa.eu/web/guest/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations>> accessed 10 August 2014

which certain stakeholder groups are marginalised or absent.”⁷⁷ It is clear that the discretion granted to ECHA as regards consultation, both in terms of when to consult and who to consult, creates the potential for a new governance failure. What this means for EU jurisprudence on soft norms is discussed in Chapter 10.

In her work on one of ECHA’s guidance documents, Korkea-aho talks of the transformation of framework norms through networked activities and practices of guidance drafting.⁷⁸ What is clear is that while the guidance documents on ECHA’s website bear ECHA’s name, they are often the product of input from multiple sources and there is, in fact, a “blurring of authorship”.⁷⁹ When one looks at the references in Korkea-aho’s case study on ECHA’s Guidance on Requirements for Substances in Articles, what is interesting is that her insights into who actually participated in the generation of that guidance document come not from public sources, but from personal communications with ECHA.⁸⁰ As Korkea-aho notes, this lack of public information on contributions during the writing of ECHA guidance stands in stark contrast to what happens with other EU environmental regimes, for example under the Water Framework Directive.⁸¹ This lack of full transparency is a potential concern both for REACH and more widely for soft, post-legislative instruments.⁸² What is also striking as regards the creation ECHA’s guidance is the lack of input from the third sector: of 20 stakeholders who formed part of the PEG for that guidance document, only one was a NGO.⁸³ However, and on an instrumental level, as discussed further in Chapter 10, the outputs of this lack of transparency and participation (i.e. the guidance documents) are themselves largely legitimate and so the lack of transparency, while not ideal, can be accepted.

⁷⁷ de Burca (n 5) 235. See also the contributions by Lisa Alexander, Wendy Bach and Mark Dawson in the same special issue of the *Wisconsin Law Review*.

⁷⁸ Korkea-aho (n 4) 365

⁷⁹ Armstrong (n 7) 257

⁸⁰ Korkea-aho (n 4) footnotes 28 and 29

⁸¹ Korkea-aho (n 4) 372

⁸² Senden (n 21) 65; Scott (n 10) 336

⁸³ Korkea-aho (n 4) 372

2. *Formats and Size*

As was noted earlier in this chapter, guidance is not monolithic and, instead, comes in a variety of forms. Just as (hard) law is pluralised and differentiated, so too are post legislative norms. ECHA produces Guidance, ‘Guidance in a Nutshell’, ‘Guidance Factsheets’, ‘Practical Guides’ and ‘Formats’,⁸⁴ together with almost 1,000 separate FAQs.⁸⁵ The breadth of the ‘guidance’ produced by ECHA and the variety of forms that ECHA’s guidance takes is striking. What is revealing is the explicit acknowledgment by the Agency of a hierarchy of soft law norms within the differing types of guidance that it produces. ECHA labels everything but the core guidance documents as “quasi-guidance”, with the intent that the latter are “in simple terms” and particularly intended for SMEs.⁸⁶ Such differentiation is not unique to ECHA, though the breadth of the differentiation is unusual. In her work on EU agencies (in general) Vos writes of their “informal law making” and comments that,

“in terms of output informality, agencies adopt a variety of informal documents, such as recommendations, opinions, standards, guidelines, guidance documents, scientific reports, codes of conduct, an annual report, a work plan and a strategic plan.”⁸⁷

Armstrong has questioned whether new governance lives up to its allegedly non-hierarchical character.⁸⁸ The thesis certainly shows that there is a hierarchy of norms in different soft post legislative formats. The different formats of ECHA’s guidance raise an interesting jurisprudential question as to hierarchy: exactly what is the legal effect of ECHA calling something ‘quasi guidance’? The answer is not clear. Certainly, there is no EU jurisprudence directly on point. Indeed, the review of the relevant case law in Chapter 4 showed that the label ‘quasi guidance’ has the potential to

⁸⁴ <<http://echa.europa.eu/support/guidance>> accessed 10 August 2014

⁸⁵ <<http://echa.europa.eu/support/qas-support/search-qas>> accessed 10 August 2014

⁸⁶ *ibid*

⁸⁷ Ellen Vos, ‘Making Informal International Law Accountable: Lessons from the EU’ in Joost Pauwelyn, Ramses Wessel, and Jan Wouters (eds) *Informal International Lawmaking* (OUP 2012) 372

⁸⁸ Armstrong (n 7); see also: Armstrong (n 59) 182

be meaningless, on a case-by-case basis, as the courts are more interested in substance over form (and so what will matter will be what that guidance does, rather than what it is called). What is also interesting is that some of ECHA's guidance documents seek to govern by design (rather than through pure advice), in offering up structures and templates for registrants:⁸⁹ thus, ECHA's so-called 'Formats' are blank templates of certain of the reports to be submitted to the Agency (e.g. the Chemical Safety Report or the Annex XV dossier on Restriction); and there are also 'Practical Examples' published by ECHA, which give illustrative examples of how completed chemical safety assessments and exposure scenarios should look.⁹⁰

Much has been made in this thesis not just about the different formats of ECHA's guidance, but also its size. Notwithstanding the length of REACH itself, the core guidance documents are almost 10 times as long as the Regulation. Adding in the 'quasi guidance' pushes this multiplier even further. Sizeable guidance documents are not the sole purview of REACH. For example, two of the guidance docs produced under the Water Framework Directive are more than 200 pages long.⁹¹ There are now 29 WFD guidance docs, plus 7 overview "policy summaries" of those guidance documents.⁹² However, while these are voluminous, they pale in comparison with REACH and there is not the same breadth of formats. The differing formats of ECHA's guidance and their size pose a normative challenge to most conventional understandings of new governance. Joerges and Weimer comment that,

⁸⁹ Armstrong (n 59) 182

⁹⁰ See: <<http://echa.europa.eu/web/guest/support/practical-examples-of-chemical-safety-reports>> accessed 10 August 2014

⁹¹ As reviewed in Trubek and Trubek (n 22) 18

⁹² See: <http://ec.europa.eu/environment/water/water-framework/facts_figures/guidance_docs_en.htm> accessed 10 August 2014

“The main thrust of the new governance paradigm of European integration was to point to the limits of traditional EU law to achieve common regulatory objectives.”⁹³

If, as shown by REACH, we have a hybrid new governance approach in which the new elements are both voluminous and hierarchical (mirroring EU hard law), does this then mean the approach has failed? Modes of new governance are seen as being more effective than traditional modes of control, as being better at problem solving. What does this then mean when, in a hybrid like REACH, the ‘new’ part (i.e. the multiple and myriad modes of guidance) in many ways reflect the ‘old’ part? That is, where the guidance is just as detailed and dense, if not more so, than the legislation, have we just created more and more complex forms of ordering and fewer/less effective forms of problem solving? I would suggest not. Though the extent of REACH’s post legislative normative ordering is striking, we should perhaps not be surprised. Legislative time is limited, and some matters will necessarily be left for further debate. At the same time, legislative knowledge at the point of law-making is incomplete and imperfect,⁹⁴ requiring elaboration in the post legislative phase. Finally, there will always be discretion in how legislative norms are interpreted, expanded on and operationalised. The very size of REACH, and the complexity of chemicals risk assessment, may be the reasons for the size and complexity of the post legislative norm elaboration. The hierarchy, density, spread and lack of flexibility in REACH’s post legislative norms may be atypical of a new governance approach but, at the same time, this thesis acts as a challenge to a number of other conventional understandings of new governance.

3. *Addressees*

The guidance produced by ECHA is intended for different addressees, explicit and implicit, and it matters to whom ECHA’s guidance is officially

⁹³ Christian Joerges and Maria Weimer, ‘A Crisis of Executive Managerialism in the EU: No Alternative?’ in Grainne de Burca, Claire Kilpatrick and Joanne Scott (eds) *Critical Legal Perspective on Global Governance: Liber Amicorum David M Trubek* (Hart 2014) 303

⁹⁴ Wilkinson (n 60) 682

addressed. In *PTC*, a Polish regulator was held by the ECJ to be unable to apply Commission guidelines on market power in electronic communications markets because those guidelines were addressed to Member State regulatory authorities and not to individuals.⁹⁵ On an explicit level, most of ECHA's guidance is addressed to registrants, aiming at assisting industry with the execution of its obligations under REACH. But there are core guidance documents aimed at Member States,⁹⁶ and at the Agency itself.⁹⁷ However, it would be foolish to ignore the fact that ECHA's guidance is also addressed (implicitly) to a wider variety of actors not named in the documents: lawyers (advising their clients on compliance and other matters); would-be entrants to the EU chemicals; Only Representatives; Third Party Registrants; NGOs/third sector actors; Member State competent authorities; and the Commission.

The language that ECHA uses in its guidance differs depending on to whom the guidance is addressed. Two comparisons are instructive. The Guidance on Information Requirements and Chemical Safety Assessment is the most dense and most technical of all that published by ECHA. It is in fact 28 separate guidance documents, amounting to more than 200,000 words of text across 2,232 pages.⁹⁸ These 28 are (implicitly) addressed to chemists and regulatory scientists and detail processes for chemicals data collection and assessment, the identification of data gaps and the subsequent generation of additional data to fill those gaps. The more accessible Guidance on Registration, however, is written for those 'with or without expert knowledge in the field of chemicals' and acts as an umbrella overview of the implementation of REACH.⁹⁹ This guidance document details helpful examples and the language used is markedly different (namely, more layperson friendly) than that used in the Guidance

⁹⁵ Case C-410/09 *Polska Teleonia Cyfrowa* [2011] ECR I-03853

⁹⁶ ECHA (n 34)

⁹⁷ ECHA, 'Procedure on Dossier Evaluation' (PRO-0017.03, July 2013)

⁹⁸ ECHA, 'Guidance on Information Requirements and Chemical Safety Assessment' (Part A, Version 1.1, December 2011). See: <<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>> accessed 10 August 2014

⁹⁹ ECHA, 'Guidance on Registration' (Version 2.0, May 2012) 11 – hereafter the 'Guidance on Registration.' See: <http://echa.europa.eu/documents/10162/13632/registration_en.pdf> accessed 10 August 2014

on Information Requirements. The Guidance on Registration takes the text of REACH and puts it into more accessible language. In striking contrast to the Guidance on Information Requirements, ECHA's Guidance on the Communication of Information on the Risks and Safe Uses of Chemicals,¹⁰⁰ addressed to Member States, is both basic and generic. Much of what is written is also suggestive: MSCAs are advised to "consider" doing X or Y on 59 separate occasions in the guidance. This suggests a reflexivity and awareness on the part of the Agency as to the impact of its guidance, and a degree of political manoeuvring. The differences in language (permissive; suggestive; technical; explanatory; reassuring etc) may also be relevant to how the different guidance documents would be adjudicated (discussed in Chapter 4).

4. *Functions*

This thesis offers up four, different functions of the guidance produced by ECHA: amplification; standardisation; translation; and extrapolation – examples of each were set out in Chapters 5-8. These functions form part of my original contribution to the existing body of scholarship on post legislative norms. Amplification occurs where guidance produced by ECHA goes beyond, but is not in direct contradiction with, the text of the Regulation. Standardisation is depicted as 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. This thesis has argued that translation occurs when, despite the text of REACH being clear, the Agency, in its guidance, implicitly contests the drafting of the Regulation and 'translates' the relevant provisions into something else. Finally, extrapolation was said to occur where REACH was silent on a particular matter that the Agency felt was important for the operation of REACH and so guidance was issued to fill in the gap. Amplification and standardisation may be seen as legitimate aims of guidance produced by an EU agency; extrapolation may be seen as

¹⁰⁰ ECHA (n 34)

necessary for the efficient working of REACH. Translation, however, is more troubling.

In terms of how these four functions differ from one another, it may be useful to think that: (a) amplification is ECHA setting out what REACH says, but in more depth; (b) standardisation is ECHA setting out what REACH requires to be done (even though the Regulation is not specific about what course of action should be taken to achieve the thing to be done); (c) translation is ECHA putting forth what REACH meant to say (but said incorrectly); and (d) extrapolation is ECHA detailing what REACH should have said (but did not). ECHA is well aware of the power it holds, in issuing guidance, to shape the operationalization of the Regulation and to set out understandings of REACH. In its revised Consultation Procedure on Guidance, ECHA states that the production of guidance, “require[s] interpretation of the underlying regulation.”¹⁰¹ In so doing, the Agency acknowledges the discretion and policy choices inherent in this process.¹⁰²

5. *Acceptance*

Save for one example (discussed below), ECHA’s guidance is presented on the Agency’s website as a suite of norms accepted by all of those involved in its creation or updating. This may, however, be misleading. A Guidance Consultation Procedure was first adopted by ECHA’s Management Board in 2008, with full implementation of the procedures and workflows for developing and updating guidance occurring in 2009.¹⁰³ ECHA’s aim with the development and review of guidance is to build consensus between various actors. This, however, is not always possible. The 2008 Guidance Consultation Procedure was said to have led to, “protracted discussions on scientific, technical or policy issues which caused delays.”¹⁰⁴ As a result, ECHA implemented a new Consultation Procedure on Guidance in 2011, which allows the Agency to, “finalise guidance on the basis of majority

¹⁰¹ ECHA (n 71) 2

¹⁰² Korkea-aho (n 4) 374

¹⁰³ ECHA, ‘General Report 2009’ (Helsinki, 2009) section 1.5

¹⁰⁴ ECHA, ‘The Operation of REACH and CLP’ (Helsinki, 2011) 47

views if full consensus cannot be achieved.”¹⁰⁵ What this means then is that, even if on the face of the guidance document it seems accepted, there could have been strong, minority views against its norm shaping. In many ways, the same is true of EU legislation. However, the difference (and it is an important difference) is that, with EU legislation, the legislative history, the differing drafts, the various debates etc are publicly available. With ECHA’s guidance, while there are some minutes published on the Agency’s website, it is very difficult to have an in-depth sense of contestation, participation and deliberation in guidance making.

ECHA’s Guidance on Requirements for Substances in Articles comes with a front page health warning that it “did not find full support by consulted national authorities.”¹⁰⁶ As such, the Agency has put out guidance which is explicitly contested. The story of this contestation is illuminating. A Swedish NGO performed a study on plastic shoes, which showed that they contained phthalates (DEHP and DBP) in very different concentrations, depending on which method of calculation one used.¹⁰⁷ Once published, and then picked up, different Member States took sides on which method of calculation was more appropriate. This story is instructive as it raises the question of how many other guidance documents might, in the future, become similarly contested through intervention/data creation by private bodies which in turn leads to disagreements in interpretation between Member States. This issue, and the disputed ECHA guidance document, is also interesting as it poses another challenge to conventional notions of hybridity, which implicitly assumes complementary and does not (explicitly) allow for contestations between yoked norms. In their work, Trubek and Trubek distinguish complementarity, rivalry and hybridity; their analysis suggesting that new approaches to governance can co-exist with more traditional forms of regulation sometimes on a complementary

¹⁰⁵ ECHA (n 71)

¹⁰⁶ ECHA, ‘Guidance on Requirements for Substances in Articles’ (Version 2, April 2011). See: <http://echa.europa.eu/documents/10162/13632/articles_en.pdf> accessed 10 August 2014

¹⁰⁷ Marianne Hoppenbrouwers, ‘The Story of the Button on the Jacket – Substances in Complex Products’ (2011) 8(4) JEEPL 353, Section 3

basis, sometimes on a rival basis and sometimes on a transformative, or hybrid basis.¹⁰⁸ Cottrell and Trubek comment that,

“The [hybrid] systems complement one another: without the standard regulatory framework entities might lack incentives to self-regulate, while without the more flexible new governance processes they would not be able to carry out innovative strategies”¹⁰⁹

In a similar vein, Armstrong writes that, “The essence of hybridity is the idea of a mutual interaction between instruments.”¹¹⁰ I would suggest that his ‘mutual interaction’ and the other conceptions are implicitly positive. Here, and with the example of the Guidance on Requirements for Substances in Articles, we see a yoked soft norm that imperfectly aligns with its backstopped hard law; there is an element of subversion going on. There is, among the Member States, and with the resultant guidance document, a rivalry of interpretations. Similarly, where ECHA’s guidance translates the text of REACH (discussed above), this is also not complementary. While others have commented on the “multiple complementary or contradictory governance modes” within the EU’s new governance approaches,¹¹¹ this thesis is the first to show, on one level, the multiple complementary *and* contradictory post legislative norm shaping within the same hybrid, yoked space. This subversion is important when it comes to consideration of the justiciability of soft norms, discussed in Chapters 4 and 10.

6. *Genesis and Competence*

The guidance that underpins REACH was born at different times, derives its authority from different provisions in the Regulation and is updated in

¹⁰⁸ Trubek et al (n 11) 21. This supposition is also suggested by the introduction, given by Grainne de Burca, to the Special Issue of the *Columbia Journal of European Law* (n 9 above) in which the Trubek and Trubek research paper appears.

¹⁰⁹ M. Patrick Cottrell and David M. Trubek, ‘Law as Problem Solving: Standards, Networks, Experimentation, and Deliberation in Global Space’ (2012) 21 *Transnational Law & Contemporary Problems* 359, 371

¹¹⁰ Armstrong (n 66) 297

¹¹¹ Armstrong and Kilpatrick (n 6) 654

differing ways. Not all of the guidance that underpins REACH was produced after the entry into force of the Regulation. Much of it (or, at least, many of the first iterations) was compiled in tandem with the negotiation of the text of the Regulation.¹¹² This is important as the notions of hybridity assume that the soft norms that are yoked onto the hard are post-legislative; other new governance work looks at soft norms that are pre legislative or extra legislative. With the REACH Implementation Projects ('RIPs'), and the development of guidance in tandem with the draft of the Regulation, what we see are co-legislative soft norms that have post legislative effect. Indeed, Recital 35 of REACH exhorts that, "Member States, the Agency and all interested parties should take full account of the results of the RIPs." This matters because all of the information related to RIPs 3 and 4 (which produced the 15 initial REACH guidance documents for industry and Member State regulators) is no longer accessible, due to the closure of the European Chemicals Bureau and its associated website.¹¹³ The guidance itself remains (housed on ECHA's website) but there is no public information on the development of the RIPs, the stakeholders engaged, the challenges encountered etc. There is an important practical learning point here, as regards transparency, in the co-legislative development of soft norms.¹¹⁴

In terms of legislative mandate for guidance, Article 77(2) details that one of the tasks of ECHA's Secretariat is to,

"... (g) provide technical and scientific guidance and tools where appropriate for the operation of this Regulation...;

h) provide technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the helpdesks established by Member States...; [and]

¹¹² See: <<http://ec.europa.eu/environment/chemicals/reach/preparing/>> accessed 10 August 2014

¹¹³ See the non-functioning <<http://ecb.jrc.it/reach-it/>> accessed 10 August 2014

¹¹⁴ Senden (n 21) 65

(i) provide guidance to stakeholders including Member State competent authorities on communication to the public of information on the risks and safe use of substances...”

This mandate is wide and non-specific. However, the Regulation then also details a small number of specific instances where the Agency is obliged to produce guidance: for example, cost sharing guidance for SIEFs,¹¹⁵ and applications for authorisation which require socio economic analysis.¹¹⁶ The creation and promulgation of guidance under REACH is both specific and generic. Earlier in this chapter, the striking breadth and volume of ECHA’s guidance was discussed. Given this breadth, and given this volume, one might question whether there is an element of competence creep in ECHA’s approach to guidance production and whether the Agency has overstepped its generic mandate to provide, “technical and scientific guidance and tools.”

7. *Impact and Coverage*

A discussion earlier in this chapter concerned the amount of guidance produced by ECHA. However, it should not be thought that the Agency’s guidance has equality of impact or coverage. In some areas (for example, on enforcement) there is little guidance. In others, it is suggested that without ECHA’s guidance REACH would simply fail. In their work on hybridity, Trubek and Trubek suggest that we see a “real transformation” where, “one system [of governance] seems to be needed for the other to become fully effective.”¹¹⁷ Of all the elements of REACH, the creation and running of SIEFs is *the* area in which guidance produced by ECHA shapes the effective day- to-day operation of the legislation, and where we may see this ‘real transformation’. However, the same is not equally true as regards other areas of REACH. Thus, the extent to which an hybrid system of new governance results in a ‘real transformation’ is variable.

In its guidance, the Agency is far more comfortable in telling registrants what to do than in giving advice on how third parties can enforce their

¹¹⁵ Article 27(1)

¹¹⁶ Annex XVI

¹¹⁷ Trubek et al (n 11) 21

entitlements under REACH. Take, for example, ECHA's Guidance on Requirements for Substances in Articles, which relates to obligations under Article 7, and Article 33 of REACH. This guidance is detailed as regards what is (and is not) an article and when (and when not) substances are intended to be released from articles. However, less than 2 of the 87 pages of the Guidance are devoted to the communication obligations in Article 33 (which give consumers rights to know about the chemical content of the products they purchase).¹¹⁸ There are also gaps in the guidance coverage offered up by the Agency; for example, ECHA has not produced guidance to assist third parties in understanding complex chemical data. While guidance produced by ECHA is detailed when it comes to business-to-business communication or compliance matters, there is little which speaks to risk communication by registrants and suppliers to employees or the general public. On the face of it, the Agency is better at, and more comfortable with, obligation based hybrids than with rights based hybrids.

Further Work

The above account of differentiation within post legislative soft norms suggests that there is further work to be done in this area by new governance scholars. Much of the existing literature on new governance is awash with dichotomies, with contrasts, with conceptual pairings: this thesis challenges new governance scholars to become more granular, more nuanced and to take a harder, closer look at exactly what is going on, particularly in modern hybrid regulatory systems. Using this thesis as a departure point for potential further work, two main avenues of inquiry are suggested; the first is socio-legal empirical work on the development and impact of guidance; the second is on other areas of law which deserve a close (or closer) look, using the differentiated, hybrid new governance lens offered up in this thesis.

Writing of her experience of ECHA's 2012 Stakeholders' Day, Korkea-aho noted the lack of reference by delegates to the text of REACH and the multiple references, instead, to ECHA's guidance.¹¹⁹ Socio-legal empirical work is needed

¹¹⁸ *ibid*, 18-19

¹¹⁹ Korkea-aho (n 4) 366

to explore exactly how those to whom guidance is addressed experience it. At the same time, the role of lawyers in new governance is worth exploring further: not just, as has been suggested elsewhere, in how their roles have changed as a result of shifts in governance (for example, away from litigation as a problem solving strategy);¹²⁰ but also in how lawyers contribute to new governance (for example, as “norm intermediaries” in shaping policy choices and drafting soft instruments).¹²¹

The documentary richness of this thesis, and the differentiation of soft law it offers up, could act as a template for further work in other areas of EU law, both within and without the environmental sphere. An easy starting point would be the similarities and differences in post legislative norm elaboration between the various regulatory regimes for which ECHA is now responsible. Even a cursory review shows that while the CLP regime appears similar to REACH as regards the legislative mandate for guidance production,¹²² how the biocidal products regime and how the Prior Informed Consent Regulation detail that guidance is to be produced are very different.¹²³ Away from environmental law, the European Aviation Safety Agency does not merely assist the Commission in exercising rule-making powers, but also directly adopts technical guidelines.¹²⁴ The European Medicines Agency is an example of an agency that has de facto engaged in issuing technical, scientific and procedural guidance concerning the implementation of the EU pharmaceutical legislative framework.¹²⁵ As discussed earlier in this chapter, the EU regulatory regimes for foods and finance also bear similarities to REACH,

¹²⁰ Lisa T Alexander, ‘Reflections on Success and Failure in New Governance and the Role of the Lawyer’ (2010) *Wisconsin Law Review* 737; Trubek Trubek (n 40) 722

¹²¹ Susan Sturm, ‘Law’s Role in Addressing Complex Discrimination’ in Laura Beth Nielsen and Robert L. Nelson (eds) *Handbook of Employment Discrimination Research* (Springer 2005)

¹²² With CLP we see specific ECHA guidance requirements (e.g. Article 10(7)) and a much more generic obligation on the Secretariat to provide, “provide industry with technical and scientific guidance and tools where appropriate on how to comply with the obligations laid down by this Regulation” (Article 50(2)). This is very similar to REACH.

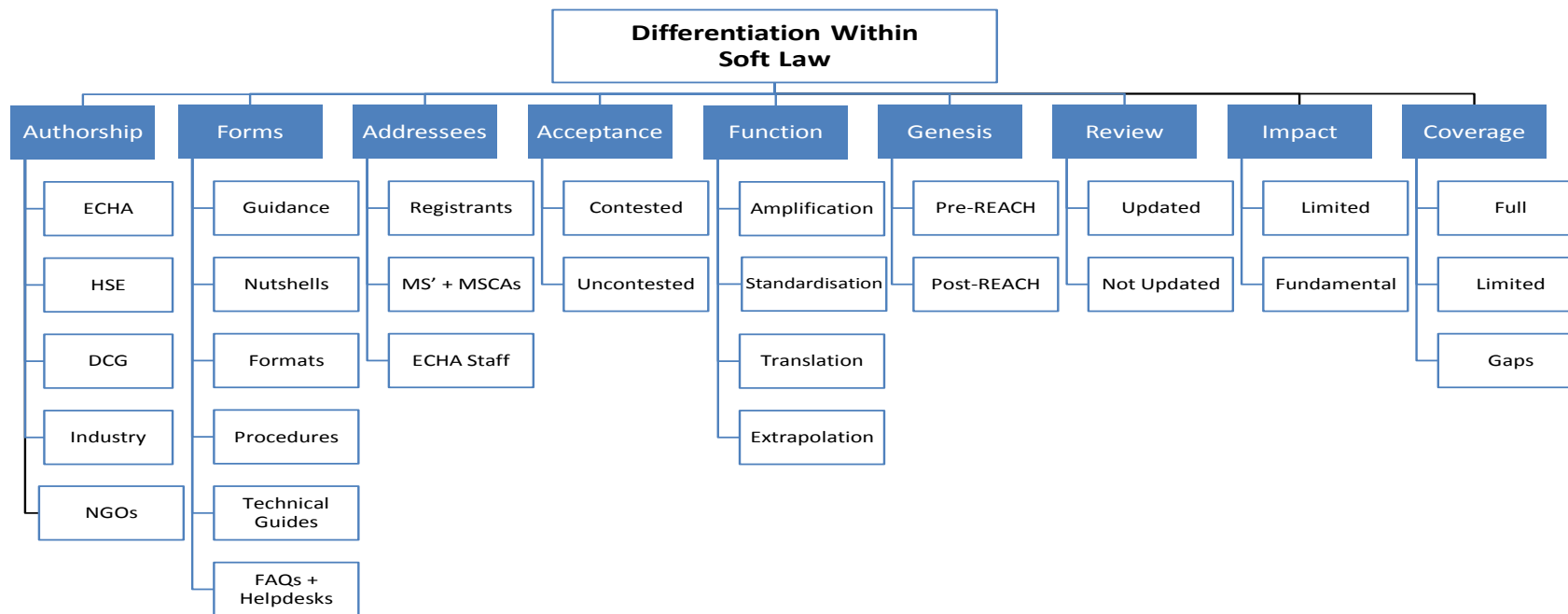
¹²³ With the Biocidal Products Regulation there is an obligation on the Commission to produce guidance (Articles 11, 24, 40, 42) and similar obligations on ECHA (Articles 54(8), 63, 76). In the Prior Informed Consent Regulation, there is somewhat odd language in Article 6(1)(c), which obliges ECHA to “where appropriate, provide, with the agreement of the Commission and after consultations with Member States, assistance and technical and scientific guidance and tools for the industry in order to ensure the effective application of this Regulation.” Linked to this is Article 13(1) which states that, “The Commission shall immediately forward to the Member States and the Agency any decision guidance documents which it receives from the Secretariat.”

¹²⁴ Senden and van den Brink (n 12) 44

¹²⁵ Edoardo Chiti, ‘European Agencies’ Rulemaking: Powers, Procedures and Assessment’ (2013) 19(1) *European Law Journal* 93

in having a strong central EU agency that issues post legislative norms. It would be interesting to apply the differentiated, pluralised account of soft law offered up in this thesis to each of those four regulators and regimes. Having set out how this thesis contributes to, and challenges, existing work on new governance the following, final Chapter brings together some overarching themes by way of conclusion.

Chart 9.1



CHAPTER 10

CONCLUSIONS

We live in a world of toxic ignorance. A world in which we are affected, on a daily basis, by chemicals. A world in which those effects are poorly understood. Over five decades, the EU has sought to better control, via regulation, the extent and nature of these impacts. Prior to 2007, the regulatory landscape within the EU for chemicals control was said, by the Royal Commission on Environmental Pollution, to be, “fragmented and differentiated.”¹ As from 2007, REACH has been the EU’s flagship chemicals’ regulation. Chemicals pervade almost every aspect of our lives and yet our knowledge of their impacts on human health and the environment is limited. REACH aims to address this data gap by transferring the regulatory burden for substance testing to the private sector and making compulsory the registration of such testing data overseen by a central EU body, ECHA. This public to private shift in responsibility for evaluating the intrinsic nature of substances is significant and reflects an (implicitly acknowledged) asymmetry of resources of financial and capital, expertise and information.

The text of REACH stands at more than 130,000 words. The most recent consolidated version of the Regulation is 516 pages long. The Regulation is complex, dense and lengthy. 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.² 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 rigorous, significant 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 5,000 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

¹ RCEP, ‘Chemicals in the Environment’ (Royal Commission on Environmental Pollution, 24th Report, 2003) 162

² See: <<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN>> accessed 10 August 2014

(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.

This thesis has provided a careful, close and detailed analysis of REACH and its guidance. It has offered up a working, four fold typology of post legislative soft norm functions (amplification; standardisation; translation; and extrapolation) and moves beyond the existing, rather blunt labels used to describe what soft norms do or can do. This thesis also challenges a number of assumptions built into work on new governance. It argues that soft law can be just as detailed and as thick as hard law, and that hierarchy and differentiation can be seen in soft norms just as they can in hard. This thesis challenges the assumption that yoked, hybrid (hard and soft) norms come only from public actors and the assumption that yoked soft norms are always complementary to their backstopped hard law. The careful documentary analysis offered up in this thesis is argued to be justification for greater granularity in new governance scholarship and a call to avoid bright line dichotomies. What is seen with REACH is more complex, more nuanced and messier than can be accounted for in simple dyads. Nuance and detail in this context are helpful because they help us to understand exactly what is going on with changes to EU norms, and the development of the EU legal order over time, and such an approach avoids scholarship based on superficial observations of governance regimes. Indeed, the use of dichotomies is highly reductive as a means of accommodating and exploring differentiation and pluralization within governance forms.³

Though the extent of REACH’s post legislative normative ordering is striking, we should perhaps not be surprised. Legislative time is limited, and some matters will necessarily be left for further debate. Equally, legislative knowledge at the point of

³ Kenneth A Armstrong, ‘The Character of EU Law and Governance: From “Community Method” to New Modes of Governance’ (2011) 64 *Current Legal Problems* 179, 206

law-making is incomplete and imperfect,⁴ requiring elaboration in the post legislative phase. In this way, post legislative guidance has the potential to act as a correcting mechanism to flaws, gaps and/or missed opportunities. Finally, there will always be discretion in how legislative norms are interpreted, expanded on and operationalised. The legislative endeavour has not necessarily failed if it is accompanied by rigorous and robust post legislative supporting norms, though such may require us to rethink soft law as a necessarily flexible panacea for hard norm deficiencies.

The work in the preceding Chapters has presented a detailed, complex, nuanced and differentiated account of hybrid new governance grounded in thick documentary analysis. This thesis has shown that the vast majority of ECHA's guidance seeks simply to amplify the text of the Regulation, or to standardise the actions of registrants (and others). Only in a handful of situations has the work in this thesis shown the Agency to have over-stepped its (admittedly wide and vague) mandate in the context of guidance production to translate the text of REACH into something very different. Similarly, only in a handful of cases has the Agency created new obligations in situations in which the Regulation is silent, (the 'extrapolation' function). We see a system of normative ordering which is both deeply hierarchical (a Regulation with a million words of guidance, plus other, less formal of shaping documents: quasi guidance, FAQs etc) and deeply heterarchical (a multitude of public and private actors all trying, in different ways, to control the operationalization of REACH). The normative landscape for chemicals regulation is played out in part in the pages of REACH, in part in the official ECHA guidance and in part in the private norms put out by Cefic and others. The yoking of post legislative norms to REACH has seen a complex transformation; one which was only partially foreseen in the Regulation (and likely also only partly foreseen in the minds of the legislature). As such, REACH is a good example of an evolving system of EU governance that is both associated with the Community Method and is also differentiated, new, complex and nuanced.

⁴ Michael Wilkinson, *Three Conceptions of Law: Towards a Jurisprudence of Democratic Experimentalism*, (2010) *Wisconsin Law Review* 673, 682

Much of the existing literature on new governance is awash with dichotomies, with contrasts, with conceptual pairings: this thesis challenges new governance scholars to become more granular, more nuanced and to take a harder, closer look at exactly what is going on in modern regulatory systems. New governance scholarship largely splits into those favouring the ‘transformation thesis’ (which argues that new approaches to governance see not only government transformed but also the nature of law itself); and those favouring the ‘gap thesis’ (which asserts that what we see with new governance is not the transformation of law but its eventual disappearance).⁵ Yoked, hybrid forms of governance (and REACH in particular) challenge both of these views to some degree. For ‘gap’ theorists, REACH as a modern, large and complex Regulation (supported by post legislative guidance) suggests not that law and new governance run in parallels but that they are often fused, though this thesis has also shown that the yoking is imperfect in a number of areas and so gaps may appear, not between the aligned-but-never-touching tracks of governance, but between the joined seams of the hybrid. With REACH, formal law is not “largely blind” to new governance, but is inextricably wound up with it, in ways foreseen (in the legislation) and unforeseen.⁶ For ‘transformation’ theorists, REACH does not necessarily demonstrate a transformation of law: instead, hybridity is (and has been shown to be) the idea of hard and soft law yoked together, not so that one automatically transforms (or has the potential to transform) the other, but so that the two work in tandem.

Armstrong has criticised scholarship on new governance for being more comfortable in “elaborating what is changing in governance compared to its conceptualisation of what is happening to law.”⁷ This thesis, and its author, do not hold indifference towards law or legal institutions. Indeed, what is so very interesting about REACH, and its operationalization, are the constellations of norms in various hybrid forms yoked on a very long, very detailed, and very

⁵ For a more detailed review of these approaches, see: Wilkinson (ibid). The work on the ‘hybrid thesis’ is much less developed. See, by way of starting point, the contributions in: Grainne de Burca and Joanne Scott (eds) *Law and New Governance in the EU and US* (Hart 2006)

⁶ Grainne de Burca and Joanne Scott, ‘Introduction’ in Grainne de Burca and Joanne Scott (eds) *Law and New Governance in the EU and US* (Hart 2006) 4

⁷ Kenneth A Armstrong, ‘New Governance and the European Union: An Empirical and Conceptual Critique’ in Grainne de Burca, Claire Kilpatrick and Joanne Scott (eds) *Critical Legal Perspective on Global Governance: Liber Amicorum David M Trubek* (Hart 2014) 249

complex piece of legislation. In some ways, the yoking of hard and soft norms makes it easier for our understandings of legality to accommodate these changes, in that questions as to the legitimacy and legality of the latter can be referred back, and set against, the former.⁸ The formal frameworks of EU law, the Treaties, do not reflect modern EU governance – as Busuioc observes, “agencification has arisen, grown and progressed in the shadow of the law, without an explicit basis in the treaties”⁹ - and there is no reference to soft law in the categories of EU Treaty norms.¹⁰ With REACH, what we see is (hard) law being elaborated on, interpreted by, pushed at, challenged and developed, to lesser and greater degrees in different situations, by norms from a number of public and private actors. What is not yet clear, given the Regulation is still largely in its infancy, is the effectiveness of those changes.

The work in this thesis also has relevance for EU jurisprudence on soft law. Five points are worth making. First, this thesis shows how soft law takes different forms and functions and that it is necessary for the judiciary to be alive to this – existing case law is rather blunt in the lenses used to conceptualise what soft law is and what functions it serves. The careful, methodical review of differentiated post legislative soft norms in this thesis may help EU judges to confront a priori assumptions about law and governance, to move them beyond “cognitive dissonance.”¹¹ In particular, the notion that post legislative soft norms *only* supplement or interpret hard law needs revisiting. Second, this thesis also highlights questions of vires – especially as regards the translation and extrapolation functions of ECHA’s guidance – with which EU judges may need to grapple. Third, even where post legislative norms are within the powers of their makers, there are key issues of reliance which give rise to legitimate expectation. This is particularly important where, as with REACH, the post legislative norms greatly outweigh the underlying hard law. The ECJ has thus far been reluctant to review post legislative norms where they are said to only “flesh out” the

⁸ That is, if we want to know whether the soft norms are legitimate, we can go back to look at the hard provisions and the underlying principles that created those provisions.

⁹ Madalina Busuioc, *European Agencies: Law and Practices of Accountability* (OUP 2013) 5

¹⁰ Linda Senden, ‘Soft Post Legislative Rulemaking: A Time for More Stringent Control’ (2013) 19(1) *European Law Journal* 57

¹¹ Joanne Scott and David M. Trubek, ‘Mind the Gap: Law and New Approaches to Governance in the EU’ (2002) 8 *European Law Journal* 1, 18

underlying hard law.¹² This must be wrong, particularly in situations where, like REACH, the fleshing out is orders of magnitude greater than the underlying hard law. Fourth, there could be a need for procedural review to ensure that actors did that which they promised to do. There is little explicit in REACH about how guidance should come into existence. Given this, the EU courts would need to refer back to general EU principles (e.g. transparency, participation). Finally, there may be overarching rights (to information, of participation etc) which could provide the basis for challenge in line with the previous point on procedural review. ECHA's Procedure on Guidance does not allow for full and fair participation by all interested groups for all guidance changes. As discussed in Chapters 4 and 9, there is a distinct lack of third sector groups as 'Accredited Stakeholder Organisations' who may participate in the production and redrafting of ECHA's guidance. Following existing ECJ jurisprudence, this raises the question of whether the stakeholders who do contribute to ECHA's guidance "taken together are sufficiently representative."¹³ The lack of transparency on Partner Expert Groups is also a potential area of challenge.

Notwithstanding the foregoing, the debate as to the legitimacy of soft law is largely academic, albeit an intellectually interesting exercise. There is nothing to suggest that use of soft law in general, and post legislative guidance in particular, will stop. At the same time, little of real substance has so far been said by the EU courts as to the uses of post legislative norms. The idea that one can rely on law and legal institutions, in particular the EU courts, to act as a check on the executive seems an instance of magical thinking, not least because of the very particular and limited way in which matters come before the courts. It would seem highly unlikely that the EU courts will move towards the "radical version" of Scott's argument for enhanced judicial review of post legislative guidance.¹⁴ At the same time, it is unlikely that the other EU institutions will act as a check on the proliferation of post legislative norm making. One only has to look to the almost

¹² Case C-325/91 *France v Commission* [1993] ECR I-3283, para 14

¹³ Case T-135/96 *UEAPME* [1998] ECR II-02335 para 90

¹⁴ Joanne Scott, 'In Legal Limbo: Post-Legislative Guidance as a Challenge for European Administrative Law' (2011) 48 *Common Market Law Review* 329, 349ff

complete lack of public interest of the Commission in ECHA's guidance, shown by the lack of coverage in the 2012 review of REACH.¹⁵

As set out above, on an empirical level this thesis shows that while there are some concerns about consultation and transparency in the production of REACH guidance, the vast majority of that guidance performs a legitimate amplification and/or standardisation function. Only a fraction of the voluminous guidance translates the underlying text into something different, or extrapolates to create obligations where none previously existed. In a world where ECHA's guidance did not exist, the effective functioning of REACH would almost certainly diminish. The lack of legal certainty would result in increased administrative burdens for ECHA and in increased costs and delays for industry. That a very small proportion of ECHA's guidance is 'bad'/illegitimate is a price worth paying. There is no real evidence of a crisis in EU law on the basis of REACH and its guidance. This work is not indifferent to issues of accountability, but does perhaps show a legal realist's preference for output legitimacy.¹⁶ Chemicals abound; so too are the norms, hard and soft, public and private, that operationalise the EU's flagship regime for chemicals control. The reach of REACH is in many ways as striking and as interesting as its legal method.

¹⁵ Commission, 'Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH: Staff Working Document (SWD (2013) 25 final) 4

¹⁶ Vivien A Schmidt, 'Democracy and Legitimacy in the European Union Revisited: Input, Output and 'Throughput'(2013) 61(1) Political Studies 2

APPENDIX 1

THE ROAD TO REACH – TIMELINE

1972	United Nations Environment Programme formed <i>Chemical pollution declared a global concern</i>
1976	Dangerous Substances Directive
1992	Intergovernmental Forum on Chemical Safety, Rio
1996	Communication on the Competitiveness of the Chemicals Industry (COM (1996) 187)
April 1998	EU Informal Environmental Council, Chester <i>Discussion of future EU chemicals policy</i>
18 November 1998	EU Commission report on implementation of four main EC chemicals legal instruments (SEC (1998) 1986)
20 December 1998	EU Council conclusions affirming need to work on future EU chemicals policy
22 February 1999	Brainstorming of Stakeholders (WRC Report RET EU 47/9)
8/9 May	EU Informal Environmental Council, Weimar <i>To discuss future EU chemicals policy</i>
26 June 1999	Environment Council conclusions (Council Document 11265/99) <i>Invited Commission to come forward with proposals by end of 2000</i>
2000	Communication on the Precautionary Principle
2001	European Environment Agency Report, Late lessons from early warnings: the precautionary principle 1896-2000

13 February 2001	EU Commission White Paper, “Strategy for a Future Chemicals Policy” COM (2001) 88 final
2 April 2001	Stakeholders Conference on White Paper
October 2001 - February 2002	Expert technical groups convened to assist in development of legislation following the White Paper
21 May 2002	Stakeholders Conference to discuss Business Impacts of the new policy
4 September 2002	World Summit on Sustainable Development, Johannesburg <i>Agreed that by 2020 chemicals will be produced and used in ways that “lead to the minimisation of significant adverse effects on human health and the environment”</i>
6 February 2006	Strategic Approach to International Chemicals Management, Dubai
7 May 2003 - 10 July 2003	Internet Consultation on workability of draft legislation
June 2003	Final Report – Impact of the New Chemicals Policy on Health and the Environment prepared by RPA and BRE Environment
September 2003	Assessment of Additional Testing Needs under REACH prepared by JRC (Institute for Health and Consumer Protection)
29 October 2003	EU Commission Proposal for REACH – COM (2003) 644 final
29 October 2003	EU Commission Staff Working Paper: REACH Extended Impact Assessment – SEC (2003) 1171/3
November 2003	A Microeconomic Model to Assess the Economic Impacts of the EU’s New Chemicals Policy (prepared by DG Enterprise)
21 November 2003	Stakeholder Workshop on the EIA of REACH
September 2004 -	REACH Trial Run #1: SPORT

June 2005	<i>Strategic Partnership on REACH Testing</i>
June 2005- December 2005	REACH Trial Run #2: <i>PRODUCE Piloting REACH for Downstream Use and Communication in Europe</i>
July 2005	REACH – Further Work on Impact Assessment: report prepared by KPMG Business Advisory Services
July 2005	JRC (IPTS) Study of the impact of REACH on new Member States
5 July 2005	SPORT Report
September 2005	Report on the “Environmental benefits of REACH”, prepared by DHI
16 December 2005	Final report on the analysis of the potential impacts of REACH on European textile supply chains
January 2006	PRODUCE Final Report
2006	Early in 2006, EU Commission Initiated the SHERPER project (SME Helpdesks – Experts Roundtable Planning their Establishment for REACH) <i>Aimed at identifying the best strategy for setting up a national helpdesk based on the needs of SMEs</i>
25 September 2006	Workshop on progress of REACH Implementation Projects for industry stakeholders <i>Also open to NGOs and Trade Unions</i>
December 2006	REACH adopted
January 2007	Report on the ““Announcement effect" in the market related to the candidate list of substances subject to authorisation” prepared by the German Institute for Environmental Strategies, Ökopol

14 February 2007	SHERPER Final Report, Berlin
February 2007	Analysis of studies discussing benefits of REACH, prepared by the German Institute for Environmental Strategies, Ökopol
June 2007	REACH enters into force

APPENDIX 2

ECHA GUIDANCE ON REACH

Name	Content	Length	Functions ¹
Guidance on Information Requirements and Chemical Safety Assessment ²	The Guidance consists of two major parts: Concise guidance (Part A to G) and supporting reference guidance (Chapters R.2 to R.20). In total, 28 separate guidance documents.	Parts A – G = 356 pages; 119,859 words. Total for this guidance: more than 700 pages; more than 200,000 words.	<ul style="list-style-type: none"> • Amplification • Standardisation (e.g. composition and content of registration dossier)
Guidance for Annex V	This document describes the exemptions from the obligation to register in accordance with Article 2(7)(b) of the REACH Regulation.	55 pages; 17,508 words	<ul style="list-style-type: none"> • Amplification
Guidance on Registration	“This document describes when and how to register a substance under REACH.”	126 pages; 53,501 words	<ul style="list-style-type: none"> • Amplification (e.g. definition of a ‘Lead Registrant’)
Guidance on Monomers and Polymers	“This document describes the specific provisions for polymers and monomers under REACH.”	26 pages; 9,268 words	<ul style="list-style-type: none"> • Amplification
Guidance on Data Sharing	“This document describes data sharing mechanisms for phase-in and non phase-in substances under REACH. It includes the communication within the SIEF and the cost sharing guidance. The document also describes the Confidential Business Information and Competition Law issues in the context of data sharing.”	148 pages; 66,286 words	<ul style="list-style-type: none"> • Amplification (e.g. assessment of data quality; role and functioning of data holders) • Standardisation (e.g. advice on consortia; use of ITPs) • Translation (e.g. point at which a SIEF is formed; how data in a SIEF should be shared)

¹ This thesis has highlighted four functions of ECHA’s guidance: amplification; standardisation; extrapolation; and translation. This column details which functions are seen with each guidance document and highlights a number of particularly noteworthy examples.

² <<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>> accessed 10 August 2014

Guidance for Identification of Substances	“This document describes how to name and identify a substance under REACH and CLP.”	118 pages; 35,423 words	<ul style="list-style-type: none"> • Amplification • Standardisation (e.g. how to determine chemical ‘sameness’) • Extrapolation (e.g. notion of UVCB substances)
Guidance on the compilation of Safety Data Sheets	This guidance provides information on issues to consider when compiling a Safety Data Sheet (an SDS), details of the requirements for information to be included within each Section of an SDS - in particular detailing the changes arising from the different revisions of Annex II of REACH and transition periods for implementation of these changes. It also gives general information on for which substances and mixtures SDSs needs to be provided and by whom.	125 pages; 49,872 words	<ul style="list-style-type: none"> • Amplification (e.g. definition of ‘competent person’) • Extrapolation (e.g. required language of SDS’)
Guidance on requirements for substances in articles	This document assists producers and importers of articles in identifying whether they have obligations under REACH; in particular in relation to registration and notification according to Article 7, and in relation to article supply chain communication according to Article 33.	87 pages; 30,188 words	<ul style="list-style-type: none"> • Amplification (e.g. how Article 33(2) works)
Guidance on preparation of an application for authorization	This document describes how to prepare an application for authorisation and provides guidance on analysis of the alternatives and substitution plan. It also describes how third parties may prepare and submit information on alternatives.	141 pages; 61,706 words	<ul style="list-style-type: none"> • Amplification • Standardisation
Guidance on Socio-Economic Analysis – Authorisation	This document assists applicants making an application for an authorisation to prepare a socio-economic analysis.	260 pages; 98,380 words	<ul style="list-style-type: none"> • Amplification • Extrapolation (e.g. requirement for SEA when adequate control demonstrated) • Translation (e.g. requirement for formal SEA when not using adequate control route/misreading of Article 65(2)(a))
Guidance on Intermediates	This document describes when and how the specific provisions for the registration of intermediates under REACH can be used.	49 pages; 17,696 words	<ul style="list-style-type: none"> • Amplification
Guidance on the Communication	This guidance document is intended to be used mainly by Member State Competent	68 pages; 23,924 words	<ul style="list-style-type: none"> • Amplification • Standardisation

of Information on the Risks and Safe Uses of Chemicals	Authorities (MSCAs) in communicating about the risks of chemicals, specifically in the context of the REACH Regulation.		(but weak, due to use of qualified language by ECHA)
Guidance on Waste and Recovered Substances	This document describes under which conditions legal entities recovering substances from waste can benefit from the exemption laid down in article 2(7)(d) of REACH and elaborates the obligation to share information in the supply chain as put forward in title IV of REACH.	36 pages; 17,775 words	<ul style="list-style-type: none"> • Amplification
Guidance on Priority Setting for Evaluation	This document describes the different priority setting methods developed to prioritise dossiers, testing proposals or substances for evaluation and gives guidance for the Agency and the Member States Competent Authorities on the application of these methods.	53 pages; 19,488 words	<ul style="list-style-type: none"> • Standardisation • Amplification • Translation (e.g. misreading of Article 41(1)/criteria for testing proposals)
Guidance on Socio-Economic Analysis – Restrictions	This document assists Member State Competent Authorities and the Agency (on a request from the Commission) in preparing and using a socio-economic analysis when developing an Annex XV dossier for Restriction. Further, it assists interested parties in preparing a socio-economic analysis or providing information in order to contribute to one.	211 pages; 79,345 words	<ul style="list-style-type: none"> • Amplification • Extrapolation (e.g. hierarchy of SEA impacts; triggers for restriction; requirement for SEA when adequate control demonstrated;
Guidance on SR&D and PPORD	This document describes specific provisions under REACH for substances manufactured, imported or used in scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD).	18 pages; 5,914 words	<ul style="list-style-type: none"> • Amplification
Guidance for Downstream Users	This document describes the roles and obligations of downstream users, and advises them on how to prepare for the implementation for REACH.	160 pages; 66,066 words	<ul style="list-style-type: none"> • Amplification
Guidance on Dossier and Substance Evaluation	This document describes the evaluation tasks to be performed by the Authorities: evaluation of testing proposals and compliance check by the Agency and substance evaluation by the Member States Competent Authorities.	139 pages; 45,983 words	<ul style="list-style-type: none"> • Amplification • Standardisation (e.g. steps to be taken by ECHA during the compliance check)
Guidance for Preparation of an Annex XV dossier on	This document describes how the authorities (Member States Competent Authorities or the Agency) can prepare an Annex XV dossier to identify a substance of very high	58 pages; 22,393 words	<ul style="list-style-type: none"> • Amplification • Standardisation • Extrapolation (e.g. consultation

Identification of SVHCs	concern.		requirement on Member States)
Guidance for Preparation of an Annex XV dossier for Restrictions	This document describes how the authorities (Member States Competent Authorities or the Agency on request from the Commission) can prepare an Annex XV dossier to propose a restriction under REACH.	130 pages; 44,141 words	<ul style="list-style-type: none"> • Amplification • Standardisation
Guidance on Inclusion of Substances in Annex XIV	This guidance document was withdrawn, but a copy of the original version is on file with the author.	12 pages; 6,048 words	<ul style="list-style-type: none"> • Not Relevant (as document withdrawn)