Steven Vaughan

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EU CHEMICALS REGULATION

New Governance, Hybridity and REACH

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Preface

After my law degree, I spent almost a decade (full-time and part-time) working as a solicitor in the City of London for two of the world's largest law firms, advising multinational clients on environmental risks. During that time, REACH was either very much on the horizon or very much front and present. Advising clients during that time allowed me to see both how complex and unwieldy the EU's flagship chemicals regime was, and how it was underpinned (and needed much more underpinning) by guidance issued both by the EU chemicals regulator ECHA and by a number of industry associations and representative bodies. I loved being a solicitor, but had always wanted to undertake doctoral study, inspired by Liz Fisher who had taught me as an undergraduate student at Oxford and who would go on to be a constant source of inspiration and encouragement in the years that followed. I met Bob Lee on a Master's degree in international environmental law offered by my first law firm. He was one of the professors in charge of the course. Over a coffee in 2007, he suggested that I move to Cardiff and undertake a PhD with him, while still working in practice part time. REACH was not necessarily my first choice for PhD topic. It is fair to say that chemicals regulation is not one of the 'hot' subjects in environmental law. It does not have quite the same cachet as, say, climate change or environmental justice. But the more I thought about a suitable topic for my PhD, the more convinced I became that REACH offered the breadth and depth to do something really interesting. At the same time, in the back of my head was a fascinating article written by Laurence Etherington on 'mandatory guidance', hierarchies in post-legislative norms and the regulation of contaminated land.[1] My doctoral research was part-funded by an ESRC 1+3 Scholarship (grant ES/F033826/1). I am very grateful for the financial support and training this offered. My PhD examiners, Joanne Scott and Veerle Heyvaert, were appropriately critical of the thesis I had submitted. With their detailed written comments, and in the viva, they enabled me to see, better than I

[1] Laurence Etherington, '"Mandatory Guidance" for dealing with Contaminated Land: Paradox or Pragmatism?' (2002) 23(3) *Statute Law Review* 203.

could for myself at the time, what I had done and where I could take my ideas. This book is of an order of magnitude more interesting and more robust for their feedback. Since my viva, Joanne has been an incredibly warm and generous source of support, and I am so very grateful for that.

Since completing my PhD, I have become increasingly interested in the practicalities of what guidance EU agencies publish, what these documents are called and what form they take, the extent to which they contain statements about their purpose or remit and the lack of consistency on these matters. While I have been publishing on REACH and chemicals regulation for a number of years as an academic,[2] this book has allowed me the space to further develop and push my ideas on EU norms, post-legislative guidance and 'new governance', underpinned by a careful, rigorous review of REACH.

There are a number of people who have supported and inspired me with this book, and whom I would like to thank. While in practice, Julie Hatcher, J.P. Poitras, Gary Gengel and Uli Börger from Latham & Watkins LLP were excellent mentors and partners. They opened me up to the interesting, complex and challenging space of chemicals regulation in general and REACH in particular, and were incredibly supportive of me doing a PhD. At Cardiff University, where I undertook my PhD, Elen Stokes was a wonderful source of encouragement and a scholar whose brilliance makes me want to be a better academic. Her advice on parts of this book has been invaluable. Leanne Smith and Richard Moorhead, one of academia's power couples, and former colleagues at Cardiff, have also been incredibly kind with their time and their advice on the work in this book. Since joining the University of Birmingham, I have found a research environment that is warm, welcoming and supportive. I am incredibly grateful for comments on various parts of this book from my colleagues Marie Fox, Tony Arnull and Graham Gee. Bob has been an exceptional mentor, on this project and in many other matters. I know that I would not be where I am today without him.

I should also thank my family. My father was always worried about me

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[2] Steven Vaughan, 'My Chemical (Regulation) Romance' (2015) *Journal of Environmental Law* forthcoming; Elen Stokes and Steven Vaughan, 'Great Expectations: 50 Years of Chemicals Legislation in the EU' (2014) 25(3) *Journal of Environmental Law* 411; Steven Vaughan, 'The Toxic Substances Control Act: A Practical Guide' (2012) 24 *Journal of Environmental Law* 581; 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; Steven Vaughan, 'Chemical Reaction' (2008) 10(24) *Legal Week* 16; Robert G. Lee and Steven Vaughan, 'Within REACH' (2008) 6 *The Chemical Engineer* 20.

working too hard in the City and was so pleased when I started the PhD. Sadly, he passed away before I had finished. Were he still around, I know that this book would have had a proud place on his bookcase, alongside every single school report I received from the age of four and every piece of university feedback, each carefully preserved by him. My husband Digby is a man of science, a GP, and finds it amusing that someone for whom toxicology is somewhat of an upwards struggle would choose chemicals as one of his primary sites of academic interest. It was his inspired idea for the chimera, a hybrid creature from Greek mythology, on the front cover.

The Moot House, Lichfield
30 December 2014

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 with the enforcement of EU chemicals regulation and nothing to do with star ratings. The following list of abbreviations provides an introduction to the main specialized terms and acronyms used in this book.

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
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'

[1] It is probably worth noting here that REACH uses the s-spelling and not the z-spelling for 'Authorisation'. The same approach is taken in this book.

	(SVHCs). If a substance is identified as a 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 L 353/1
CMR	Carcinogenic, Mutagenic or Toxic to Reproduction
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
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
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
GHS	Globally Harmonized System of Classification

	and Labelling of Chemicals. Developed by the United Nations
GLP	Good Laboratory Practice
HPV	High Production Volume. HPV was used in pre-REACH EU chemicals legislation for substances manufactured annually in volumes of more than 1000 tonnes. The term is no longer relevant under REACH, but it is currently still used for the global risk assessment of chemicals e.g. by the Organisation for Economic Co-operation and Development
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
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
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 3400 '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 67/548/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'

OEL	Occupational Exposure Limit
OR	Only Representative
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 characterized 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
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
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
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
Substitution	Principle of REACH which seeks to replace harmful chemicals on the EU market with less harmful alternatives
SVHC	Substance of Very High Concern
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'
UVCB	Unknown or Variable Composition
vPvB	Very Persistent and Very Bioaccumulative

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