

PETER FISK ASSOCIATES LTD

Chemical Risk Assessment

A Manual for REACH

WILEY

Chemical Risk Assessment

Chemical Risk Assessment: A Manual for REACH

Peter Fisk Associates Ltd

WILEY

This edition first published 2014
© 2014 John Wiley and Sons Ltd

Registered office

John Wiley & Sons Ltd, The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, United Kingdom

For details of our global editorial offices, for customer services and for information about how to apply for permission to reuse the copyright material in this book please see our website at www.wiley.com.

The right of the author to be identified as the author of this work has been asserted in accordance with the Copyright, Designs and Patents Act 1988.

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, except as permitted by the UK Copyright, Designs and Patents Act 1988, without the prior permission of the publisher.

Wiley also publishes its books in a variety of electronic formats. Some content that appears in print may not be available in electronic books.

Designations used by companies to distinguish their products are often claimed as trademarks. All brand names and product names used in this book are trade names, service marks, trademarks or registered trademarks of their respective owners. The publisher is not associated with any product or vendor mentioned in this book. This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold on the understanding that the publisher is not engaged in rendering professional services. If professional advice or other expert assistance is required, the services of a competent professional should be sought.

Limit of Liability/Disclaimer of Warranty: While the publisher and author have used their best efforts in preparing this book, they make no representations or warranties with respect to the accuracy or completeness of the contents of this book and specifically disclaim any implied warranties of merchantability or fitness for a particular purpose. It is sold on the understanding that the publisher is not engaged in rendering professional services and neither the publisher nor the author shall be liable for damages arising herefrom. If professional advice or other expert assistance is required, the services of a competent professional should be sought.

The advice and strategies contained herein may not be suitable for every situation. In view of ongoing research, equipment modifications, changes in governmental regulations, and the constant flow of information relating to the use of experimental reagents, equipment, and devices, the reader is urged to review and evaluate the information provided in the package insert or instructions for each chemical, piece of equipment, reagent, or device for, among other things, any changes in the instructions or indication of usage and for added warnings and precautions. The fact that an organization or Website is referred to in this work as a citation and/or a potential source of further information does not mean that the author or the publisher endorses the information the organization or Website may provide or recommendations it may make. Further, readers should be aware that Internet Websites listed in this work may have changed or disappeared between when this work was written and when it is read. No warranty may be created or extended by any promotional statements for this work. Neither the publisher nor the author shall be liable for any damages arising herefrom.

Library of Congress Cataloging-in-Publication Data

Chemical risk assessment : a manual for REACH / Peter Fisk Associates Ltd.

pages cm

Includes index.

ISBN 978-1-119-95368-5 (cloth)

1. Chemicals—Law and legislation—European Union countries.
2. Chemicals—Safety regulations—European Union countries.
3. Hazardous substances—Law and legislation—European Union countries.

I. Peter Fisk Associates.

KJE6011.C44 2014

363.17'91 – dc23

2013028620

A catalogue record for this book is available from the British Library.

ISBN: 9781119953685

Typeset in 10/12 Times by Laserwords Private Limited, Chennai, India.

1 2014

Contents

<i>List of Figures</i>	xv
<i>List of Tables</i>	xvii
<i>List of Contributors</i>	xix
<i>Preface</i>	xxi

1. Introduction: Policy and Scientific Context of Chemicals Risk and Risk Management	1
1.1 Overview of the Risk Assessment of Chemical Substances	4
1.2 Chemical Hazard and Risk Programmes	5
1.2.1 REACH Overview	5
1.2.2 Registration	6
1.2.3 Evaluation	8
1.2.4 Authorisation and Restriction	11
1.2.5 Hazard and Risk Communication	14
1.2.6 Hazards	16
1.2.7 Overview of Types of Exposure	17
1.2.8 Overview of Risk Characterisation	19
1.2.9 Successful Interaction with REACH: Registration, Evaluation and Authorisation	21
1.2.10 Regulation and Assessment of Hazardous Chemicals Outside of the European Union	24
2. Roles and Responsibilities in REACH	39
2.1 The Structure and Responsibilities of the Authorities	39
2.1.1 Role of the ECHA	39
2.1.2 The Role of the Member State Committee (MSC)	40
2.1.3 The Role of the Member State Competent Authorities (MSCA)	40
2.2 Forum Enforcement Project – REACH-EN-FORCE-1	41
2.3 Future Aims of the HSE (an Example of a ECHA-Related Authority Acting in the UK)	41
2.4 What Does REACH Require as Regards Enforcement?	41
2.5 What Powers Do Enforcing Authorities Have?	42
2.6 The Responsibilities of Industry	42
2.6.1 Responsibilities of the Manufacturer	42
2.6.2 Responsibilities of the Importer	43

2.6.3	The Only Representative	43
2.6.4	Responsibilities of the Downstream User	43
2.7	Communication in the Supply Chain and with Regulators	44
2.7.1	Use Descriptor System	44
3.	Control of Chemicals – Legislative and Policy Context	57
3.1	How EU Chemical Legislation Evolved	57
3.2	Air Quality Regulations	63
3.3	Water Framework Directive	64
3.4	Carcinogens at Work	65
3.5	Cosmetics	66
3.6	Biocidal and Plant Protection Products	67
3.7	Nationally (UK)-Implemented Legislative and Policy Frameworks	68
3.7.1	Workplace Exposure	68
3.7.2	Control of Substances Hazardous to Health Regulations (COSHH) 2002	69
3.7.3	Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) 2002	72
3.8	UK Environmental Regulation	74
3.8.1	Overview and IPPC	74
3.8.2	Waste (England and Wales) Regulations 2011 SI 988	75
3.8.3	Water Legislation in the UK	75
3.8.4	Directive 2006/118/EC on the Protection of Groundwater against Pollution and Deterioration	77
3.8.5	Groundwater (England and Wales) Regulations 2009 (SI 2009 No. 2902)	77
3.8.6	Air Legislation in the UK	77
4.	Identification of Substances for REACH – Practicalities	81
4.1	Substance Identification	81
4.1.1	Types of Substances	82
4.1.2	Mono-Constituent Substances	82
4.1.3	Multi-Constituent Substances (MCSs)	82
4.1.4	Substances with Unknown or Variable Composition, or of Biological Origin (UVCBs)	82
4.1.5	Nanomaterials	83
4.1.6	Articles	84
4.1.7	EC Number	84
4.2	Sameness	85
4.3	Essentially-Pure Substances	85
4.4	Approaching the Substance Data Set – Understanding the Substance	86
5.	Physico-Chemical Properties for REACH – Purpose and Practicalities	89
5.1	Physico-Chemical Properties	89
5.2	Strategy in Physico-Chemical Testing Plans	91
5.2.1	Tier 1 Tests	91

5.2.2	Tier 2 Tests	92
5.2.3	Tier 3 Tests	93
5.3	Difficult-to-Measure Substances	94
5.3.1	Multiconstituent or UVCB Substances (Mixtures)	94
5.3.2	Poorly Soluble Substances	94
5.3.3	Volatile Substances	94
5.3.4	Unstable Substances Either by Hydrolysis, Photolysis or Oxidation	94
5.3.5	Ionisable Substances	95
5.3.6	Surface Active Substances	95
5.4	Hazardous Physico-Chemical Data	95
5.5	Relationship between Physico-Chemical Tests	95
5.6	Application of Physico-Chemical Test Data	96
5.7	Can Physico-Chemical Tests Be Omitted?	96
5.8	(Q)SAR and Physico-Chemical Tests	97
5.9	(Quantitative) Structure-Activity Relationships ((Q)SAR)	97
6.	Assessing and Documenting the Intrinsic Properties of Substances in REACH	103
6.1	Introduction to REACH Data Requirements	103
6.1.1	Strictly Controlled Conditions	104
6.2	Hazards	108
6.3	PBT	108
6.4	Equivalent Concern	109
6.4.1	Adversity	109
6.4.2	Mode of Action	110
6.5	Test Proposal Rule	110
6.6	Availability of Existing Data and Rights of Access	111
6.7	Data Reliability	111
6.8	Data Gaps – Options for Surrogate Data for Description of Hazard and Risk – Including Read-Across	111
6.9	Read-Across	113
7.	Assessing Environmental Properties Data	115
7.1	Environmental Properties Data	115
7.1.1	PNECs	115
7.1.2	Classification and Labelling (C&L)	116
7.1.3	PBT	116
7.2	Environmental Fate	116
7.2.1	Degradation	117
7.2.2	Bioaccumulation	120
7.2.3	Adsorption	121
7.3	Ecotoxicology	123
7.3.1	Introduction	123
7.3.2	Hazard Assessment and Risk Characterisation	123
7.3.3	Data Review	127

7.3.4	Testing of Difficult Substances	127
7.3.5	(Q)SARs, Data Waiving and EPM	128
7.3.6	Further Testing	129
7.3.7	Toxicity to Sewage Treatment Plant Microorganisms	129
7.4	Turning Intrinsic Properties into 'No-Effect' Concentrations	130
7.4.1	Selecting a Suitable Starting Point for a PNEC Calculation	131
7.4.2	Calculating a PNEC Using Assessment Factors	131
7.4.3	Calculating a PNEC Using Sensitivity Distribution	133
7.4.4	Calculating a PNEC Using Equilibrium Partitioning	133
7.4.5	Intermittent versus Continuous Releases	134
8.	Environmental Exposure	137
8.1	Substance Identity and Approach to Exposure Assessment	137
8.2	Characterising Releases	138
8.2.1	Evaluating Use Pattern	138
8.3	Evaluating Releases	139
8.3.1	Reality Checking – Top Down and Bottom Up	141
8.4	Documentation for the Registration	142
8.4.1	Uncertainty	142
8.5	Local Scale Releases	142
8.5.1	Site Size	142
8.5.2	Site Inspections	143
8.6	Exposure Assessment – Models or Measurements?	143
8.6.1	Using Measurements	143
8.6.2	Using Models	145
8.6.3	Models or Measurements – Recommended Approach	145
8.6.4	Tools	145
8.7	Water	146
8.7.1	Release via Waste-Water	146
8.7.2	River Environment	148
8.7.3	Marine Environment	149
8.7.4	Sediments	149
8.8	Soil	149
8.8.1	WWTP Sludge and Agricultural Soil	149
8.8.2	Deposition	149
8.8.3	Biodegradation in Soil	150
8.8.4	Crops and Grassland	150
8.8.5	Industrial Soil	150
8.9	Air	150
8.9.1	Air in the Standard PEC Models	150
8.9.2	Ozone Depletion and Other Specific Effects	150
8.9.3	Long Range Pollutants	151
8.10	The Food Chain	151
8.10.1	Biomagnification	151
8.10.2	Secondary Poisoning	151

9. Assessing the Hazards to Human Health from Chemicals	153
9.1 Mammalian Toxicology	153
9.2 Exposure Routes and Local/Systemic Effect Types	153
9.3 Acute and Chronic Effects	154
9.4 Influences on Toxicity	154
9.5 How Chemicals Cause Harm	155
9.5.1 Asphyxiants	155
9.5.2 Narcotics	155
9.5.3 Irritants and Corrosives	155
9.5.4 Sensitisation (Allergic Reactions)	156
9.5.5 Carcinogenicity	156
9.5.6 Genotoxic Effects	157
9.5.7 Reproductive and Developmental Effects	157
9.5.8 Target Organ Effects	157
9.6 Toxicokinetics	157
9.7 Toxicological Testing	158
9.7.1 Data Gaps	159
9.7.2 Data Waiving	159
9.7.3 Acute Toxicity Studies	159
9.7.4 Short-Term, Repeated Dose Studies	160
9.7.5 Long-Term (Chronic) Studies	160
9.7.6 Other Systemic Effects	161
9.7.7 Local Effects	162
9.8 Genetic Toxicology	162
9.8.1 Introduction	162
9.8.2 Hazard Assessment	163
9.8.3 Risk Assessment	166
9.9 Turning Intrinsic Properties into 'No-Effect' Levels	166
9.9.1 Special Cases	169
10. Human Exposure to Chemicals	171
10.1 Exposure	171
10.2 Exposure to Chemicals in the Workplace	173
10.2.1 First Tier Models	173
10.2.2 Higher Tier Models	174
10.2.3 Risk Management Measures	174
10.2.4 Exposure in the Professional Use Setting	175
10.2.5 Models	176
10.2.6 Measurements	178
10.3 Risk Management Measures	179
10.4 Consumer Exposure	179
10.4.1 General Considerations for Exposure Estimation for Consumers	180
10.4.2 Tier 1 Models	180

10.4.3	Refinement of Initial Exposure Estimates, Higher Tier Models and Measurements	181
10.4.4	Risk Management Measures – Consumers	181
10.5	Indirect Exposure (Humans via the Environment)	182
10.6	Risk due to Physico-Chemical Hazard	182
11.	Managing Hazard and Risk	185
11.1	Characterisation, Assessment and Management of Risk	185
11.2	What Is ‘Risk’ under REACH?	186
11.3	What Are Risk Reduction and Risk Management?	187
11.3.1	Risk	187
11.3.2	How Can Risks Be Controlled Adequately?	189
11.4	Where Safe Levels Cannot Be Established – CMRs and PBTs (and vPvBs)	190
11.5	Responsibilities in the Supply Chain – Introduction	190
11.6	Regulatory Requirements	191
11.7	Guidance	193
11.8	The Extended Safety Data Sheet	193
11.8.1	Current issues surrounding the use of eSDS by DUs	194
11.9	When Communication Is Difficult	194
11.10	Exposure Measurements in the Workplace – Occupational Hygiene	195
11.11	Control of Environmental Releases – Abatement Techniques	196
11.11.1	Engineering Controls	196
11.11.2	Enclosure and Containment	197
11.11.3	Bunding	197
11.11.4	Dedicated Equipment	197
11.11.5	Investment and Scale of Use – Economic Viability	197
11.11.6	Waste Stream Treatments	197
11.11.7	WWTP Treatments	198
11.11.8	Custom and Practise	198
11.11.9	Handling Standards	198
11.11.10	Clean-Down Practises	198
11.12	Effectiveness of Risk Reduction – Risk Management Options	200
11.13	Types of Risk Management – in the Workplace	201
11.13.1	Options Overview	202
11.13.2	Understanding Assumptions and Critical Issues	202
11.13.3	Risk Management Measures	202
11.14	Types of Risk Management – for the Environment	203
11.14.1	Unacceptable Risk	203
11.14.2	Options Overview	203
11.14.3	When a Data Set Is Not Complete	204
11.14.4	When a Data Set Is as Complete as It Can Be	204
11.14.5	Understanding Assumptions and Critical Issues	204
11.14.6	Strategies to Reduce the Amount of Substance Released to the Environment	204
11.15	Consumer Protection	205

12. Avoiding the Use of Hazardous Substances: Substitution and Alternatives	207
12.1 Properties That Contribute to Hazard and Risk for Human Health and the Environment	209
12.2 Assessment of Alternatives – Replacement of Use	210
12.3 What Is an Alternative?	211
12.4 Analysis of Alternatives	211
12.5 Substitution – Replacement with Substances of Reduced Hazard	211
12.5.1 Examples of Voluntary Substitution	212
12.5.2 Regulation-Led Substitution – Case Studies	213
12.6 Sustainability and Green Chemistry	218
12.7 What Is Green Chemistry in Practice? Principles and Concepts	219
12.7.1 Why Is Green Chemistry Important?	220
12.7.2 Research in Green Chemistry	220
12.7.3 Substance Design	220
12.7.4 Process Design	222
13. Hazards, Risks and Impacts – The Development and Application of Frameworks for the Assessment of Risk	225
13.1 Policy Context – Risk, Hazard and the Precautionary Principle	226
13.1.1 Assessment Frameworks – Hazard and Risk and Impacts	230
13.1.2 Precaution – Where No Safe Level Can Be Established	232
13.1.3 Application of Assessment Frameworks to Human Health and Environmental Protection	234
13.2 From Hazards to Risks to Impacts – Understanding the Implications of Exposure to Dangerous Chemicals	235
13.2.1 Introduction: The Need for a Culture of Safety	236
13.2.2 Responsible Care®	238
13.2.3 Standards and Management Tools	239
13.2.4 Risk Control and Management	241
13.2.5 Risk Control and Management in REACH	241
13.3 Risk Management Options – REACH Processes for Control of Hazardous and Risky Substances	244
13.3.1 Restrictions and Authorisations in REACH	244
13.3.2 Restrictions	246
13.3.3 Authorisations	247
14. Socio-Economic Analysis in REACH	251
14.1 Background – the Need for and Development of Socio-Economic Analysis in the Regulation of Chemicals	253
14.2 What Is SEA and Why Is It Needed and Applied in REACH?	254
14.2.1 What Is SEA within REACH?	254
14.3 Role, Purpose and Performing an SEA in REACH	255
14.3.1 Role and Purpose of an SEA in REACH	255
14.3.2 Doing an SEA in REACH	256
14.4 The Difficulties of Moving from Risks to Impacts	256

14.5	Regulatory Processes – Who Are the Decision Makers and What Are Their Roles?	265
14.6	The Wider Benefits of Performing an SEA	265
14.7	Developments and the Future	267
15.	REACH: How It Is Working and May Develop	269
15.1	Introduction	269
15.2	Experiences and Observations	269
15.2.1	Observations	270
15.3	Basics of Successful Submission	271
15.4	Testing, Prediction and Read-Across	271
15.5	The Community Rolling Action Plan	272
15.6	EU and National Responsibilities	272
15.7	Risk-Based Regulation and the Precautionary Approach	272
15.8	Higher Tiers of Assessment	273
15.9	REACH Developments	274
15.9.1	Methods of Operation and Constant Change	274
15.9.2	Improved Efficiency of Operation	275
15.9.3	Increased Scope	275
15.9.4	Policy Development on the Control of Chemicals – EU and Global Perspectives	276
15.10	Rationalising Overlap with Other Legislation	276
15.11	Scientific Developments and Challenges	278
15.12	Impact on Industry	278
15.12.1	Manufacturers and Importers	278
15.12.2	Downstream Users and Consumers	278
15.12.3	Innovation	279
15.13	ECHA Evaluation Report 2012	279
16.	Resources, Official Guidance, Further Reading and Centres of Expertise	283
16.1	Introduction to Resources and Organisations	283
16.1.1	Official Journal	283
16.1.2	ECHA and REACH-IT	284
16.1.3	CEFIC and Sector Groups	285
16.1.4	IUCLID Guidance	285
16.1.5	ECETOC	286
16.1.6	OECD	286
16.1.7	EU JRC	286
16.2	Facts and Statistics	286
Appendix A	Substance Classification and Labelling under REACH	317
A.1	Important Differences	319
A.1.1	Physico-Chemical Hazards	320
A.1.2	Health Hazards	320
A.1.3	Environmental Hazards	321

A.1.4	Supplementary Labelling Requirements under the CLP Regulations	321
A.2	CLP Symbols	322
A.2.1	Comparison of DSP/DPD with CLP 2008	325
A.3	Specific Target Organ Systemic Toxicity – Single Exposure	334
A.3.1	Carcinogenic Substances	335
A.3.2	Mutagenic Substances	337
A.3.3	Effect during Lactation	337
A.3.4	Aquatic Environment	338
A.3.5	Ozone	338
A.4	Harmonised Classification and Labelling	339
Appendix B	Further Discussion of Substance Identification and Sameness	341
B.1	Substance Identifiers	341
B.1.1	EC Name	341
B.1.2	CAS Registry Number (CAS# or CAS No.)	341
B.1.3	SMILES	341
B.1.4	InChI	342
B.2	Substance Analysis	342
B.2.1	Sameness	343
B.2.2	Impurities	344
B.2.3	Departures from the Agreed Norm	344
B.3	Straightforward Organic Substances	345
B.3.1	Identity	345
B.3.2	Purity and Characterisation	346
B.4	Complex Organic Substances	347
B.5	Inorganic Substances	348
B.5.1	Structure	349
B.5.2	Elemental Quantification	349
B.6	Analysis of UVCBs	349
Appendix C	Tools for REACH Compliance: IUCLID, Chesar and In-House Databases	351
C.1	International Uniform Chemical Information Database (IUCLID)	351
C.2	IUCLID and PPORDs	354
C.3	Submission of PPORD to ECHA	354
C.3.1	IUCLID Submission	354
C.3.2	Notification by REACH-IT	355
C.4	Chesar	356
C.4.1	Introduction	356
C.4.2	Chesar Functionalities or Organisation of the Tool	356
C.4.3	Assessment workflow of Chesar	358
C.5	Advice on Storing of Data Outside of the IUCLID	358
C.5.1	Structure	359
C.5.2	Identifiers	360
C.5.3	Mechanistic Issues	360

C.5.4	Identification and Expression of Substance Identity	361
C.5.5	Result Values	361
C.5.6	SMILES and Textual Representations of Structure	361
C.5.7	Modifications to the Data Set	361
C.5.8	Composited Fields and Repeated Processes	361
C.5.9	Duplicates	362
C.5.10	Validation	362
C.5.11	Checking	363
C.5.12	Study Reports and Cataloguing	363
C.5.13	Snapshots and Backups	364
Appendix D Glossary		365
<i>Index</i>		383

List of Figures

Figure 1.1	REACH Overview	6
Figure 1.2	Flow Diagram of SVHC, Placing on ANNEX XIV, Authorisation and Review Process	12
Figure 1.3	Flow Diagram of CoRAP, ANNEX XV Dossier and Placing on ANNEX XVII, Restriction Process	14
Figure 1.4	Overview of Substance Use Patterns	14
Figure 7.1	Flow Chart Illustrating the Processes in a Chemical Safety Assessment	124
Figure 12.1	Overview of Substance Substitution	210
Figure 13.1	A Simplified Risk Assessment Framework, with Areas of Uncertainty	228
Figure 13.2	A Simple Illustration of Source, Pathway, Receptor and Impact	235
Figure 14.1	Illustration of the Main Processes and Steps in an Authorisation SEA (adapted from Nickel Institute, 2012)	257
Figure 14.2	Total Economic Value	263
Figure 14.3	Illustration of a Possible Authorisation Timeline with Actions for Applicant, Regulator and Interested/Third Party	266
Figure B.1	Decision Tree for a Straightforward Organic Substance	348
Figure C.1	Overview of Assessment Workflow of Chesar. (Source: http://chesar.echa.europa.eu/web/chesar/support/manuals-tutorials , last accessed 5 August 2013.)	359

List of Tables

Table 1.1	Relation to REACH of chemical risk management	25
Table 1.2	Examples of regulatory systems for hazardous chemicals outside EU	27
Table 1.3	Definitions of the Klimisch reliability codes	37
Table 2.1	Regulatory authorities in the United Kingdom	42
Table 2.2	Descriptor list for sectors of use (SU)	45
Table 2.3	Descriptor list for chemical product categories (PC)	46
Table 2.4	Descriptor list for process categories (PROC)	47
Table 2.5	Descriptor list for environmental release categories (ERC)	51
Table 2.6	Descriptor list for substances in articles (AC)	54
Table 3.1	Relation to REACH of chemical risk management	61
Table 5.1	Discussion of the use of (Q)SAR for different endpoints	98
Table 5.2	Examples of common predictive methods in different endpoints	101
Table 6.1	Reach data requirements	105
Table 6.2	Key terms	112
Table 6.3	Example of read-across	113
Table 7.1	Studies required for each REACH Annex level	125
Table 8.1	Useful sources of published information for environmental exposure	139
Table 8.2	Definitions of some terms relevant to modelling or measuring exposure	144
Table 9.1	Definitions of types of toxicity relevant in REACH and CLP	155
Table 9.2	Studies required for each REACH Annex level	163
Table 9.3	<i>In vivo</i> testing in REACH	165
Table 11.1	Example problems with DU communication with possible solutions	195
Table 11.2	Summary of typical efficacies of possible abatement measures	200
Table 13.1	Environmental impact of chemical contaminants	238
Table 13.2	How REACH was implemented	242
Table 14.1	Actors and roles for the SEA	257
Table 16.1	Guidance on general needs and registration of specific chemical types	287
Table 16.2	Guidance and resources on property data	292
Table 16.3	Guidance and resources on hazard assessment, PBT and classification and labelling	296
Table 16.4	Guidance and resources on exposure and risk	300

Table 16.5	Guidance and resources on roles and responsibilities of parties in a supply chain, and communication between them	305
Table 16.6	Guidance and resources on interaction between registrants	309
Table 16.7	Guidance and resources on submitting the registration within REACH-IT	311
Table 16.8	Guidance and resources post-registration	314
Table A.1	Generic cut-off values. There are some endpoints with different concentration cut-off values	318
Table A.2	CLP symbols	323
Table A.3	Organic peroxides	327
Table A.4	Oxidising gas	328
Table A.5	Oxidising liquid	328
Table A.6	Oxidising solid	329
Table A.7	Corrosive to metals	329
Table A.8	Flammable gas	329
Table A.9	Flammable liquid	330
Table A.10	Flammable solid	330
Table A.11	Acute oral toxicity	331
Table A.12	Acute toxicity dermal	331
Table A.13	Acute toxicity by the inhalation of a dust or mist	331
Table A.14	Acute toxicity inhalation of a vapour	331
Table A.15	Acute toxicity inhalation of a gas	331
Table A.16	Aspiration hazards	332
Table A.17	Skin corrosion/irritation	332
Table A.18	Eye irritation	333
Table A.19	Respiratory sensitisation	333
Table A.20	Skin sensitisation	334
Table A.21	Specific target systemic toxicity – repeated exposure (STOT RE)	335
Table A.22	Specific target organ systemic toxicity – single exposure (STOT SE)	335
Table A.23	Carcinogenic substances	336
Table A.24	Substances toxic for reproduction	336
Table A.25	Mutagenic substances	337
Table A.26	Effect during lactation	337
Table A.27	Aquatic environment	338
Table A.28	Criteria for the aquatic environment chronic category	338
Table A.29	Ozone	338
Table B.1	The subdivision of EC numbers	342
Table B.2	Generic cut-off values	344

List of Contributors

Peter Fisk Associates includes the following staff members who have contributed to this book:

Peter Fisk – Managing Director

Oliver Warwick – Project Manager

Louise McLaughlin – Director

Rosalind Wildey – Director

Principal Consultants:

Helen Disley

Stephen Summerfield

Andrew Girling

Laura Robinson

Helen Barnes

Senior Consultants:

David Akinosho

Lucy Wilmot

Ola Dosunmu

Elina Kansikas

Sam Fisk

Consultants:

Gillian Federici

Additional Contributors:

Michel De Poortere by kind permission of Siletz sprl

Rohit Mistry by kind permission of eftec

Preface

How to Use This Book

This book about REACH is a handbook, providing practical advice aimed at the level of consideration of strategy, technical insights, and commercial realities. It does not intend to reproduce or summarise the official detailed guidance – of which there are many thousands of pages! Although that level of detail and amount of guidance is necessary, the abundance of guidance can in itself create problems. It is not possible for a single individual to absorb and understand such a huge amount of information, especially considering the diversity of issues concerning chemical properties, hazards, and risks. This book can help you understand REACH, whatever your responsibilities or interest in it.

What this handbook does do is provide a broad overview, but one that includes the details that the authors have found necessary in their experience in practice of all aspects of the REACH Regulation. The purpose of the book is to explain how REACH works, with an emphasis on an overall understanding and explanation of responsibilities, in order to help you to set strategy and priorities.

What is REACH Trying to Achieve?

REACH has many objectives, contained within what is one of the most comprehensive pieces of legislation ever enacted in the European Union. Its major objectives include:

- bringing all REACH-relevant substances, regardless of whether they have been previously assessed or not, into a common registration and evaluation process;
- moving the burden of responsibility more clearly into the hands of industry;
- placing priority of effort onto substances of very high concern;
- improving communication in the supply chain;
- encouraging the sharing of data between data owners;
- widening the availability of data on substances;
- removing unacceptably hazardous substances from the market.

How Can This Book Help You Understand REACH and Comply With It?

This book will help you to understand your part in REACH:

- **Policy maker** – business strategy in the chemicals industry in the European Union requires an awareness of the costs and impacts of REACH. This involves understanding

the current and potential status of substances under REACH, and also how other related legislation may be affected.

- **Business manager** – if you are developing a substance or group of substances you will have to understand REACH, to ensure that appropriate and timely actions on substance are taken.
- **Scientist in R&D** – it is not possible to maintain the view that R&D can be seen as separate from acceptability in commercial and regulatory terms – you need to be informed about REACH and its impacts on substances with potentially hazardous properties.
- **Regulator** – if you are not working on REACH, then this book can help you understand how your work interfaces with REACH.
- **Specialist or Consultant** – you need to know where your speciality fits into the bigger picture of REACH.

How This Book is Set Out

Chapter Summary

Chapter	Title	Summary of contents
1	Introduction – policy and scientific context of chemicals risk and risk management.	An overview of REACH and other regulations, describing the purposes of hazard and risk assessment.
2	Roles and responsibilities in REACH.	What the supply chain and the various regulatory bodies must do.
3	Control of chemicals – legislative and policy context.	What REACH requires and where it fits in a global context.
4	Identification of substances for REACH – practicalities.	An introduction to a key step in establishing what needs to be done in REACH compliance.
5	Physico-chemical properties for REACH – purpose and practicalities.	These properties need to be understood before moving on to toxicology and environmental effects.
6	Assessing and documenting the intrinsic properties of substances in REACH.	Overview of REACH requirements in respect of the basics of how hazards and risks are assessed.
7	Overview of the assessment of the risks to the environment from chemicals.	Detail of REACH requirements in respect of the basics of how environmental hazards are assessed.
8	Environmental exposure.	Detail of REACH requirements in respect of the basics of how environmental exposures and risks are assessed.

Chapter	Title	Summary of contents
9	Assessing the hazards to human health from chemicals.	Detail of REACH requirements in respect of the basics of how hazards are assessed.
10	Human exposure to chemicals.	Detail of REACH requirements in respect of the basics of how environmental exposures and risks are assessed.
11	Managing hazard and risk.	How to deal with management of hazard in respect of classification and labelling, and controlling exposure to substances to the level necessary to establish safety.
12	Avoiding the use of hazardous substances: substitution and alternatives.	Overview of how to find viable alternatives to hazardous substances, in terms of new substances or technologies.
13	Hazards, risks and impacts – the development and application of frameworks for the assessment of risk.	Risk management options: how can risk be managed, appraisal of methods to control risk and the time and costs needed for implementation of control measures.
14	Socio-economic analysis in REACH.	The need for assessing the costs and benefits of control measures using socio-economic analysis as a tool in the context of the authorisation, restriction and risk management option appraisal processes of REACH.
15	REACH: how it is working and may develop.	What has worked well, what is failing. Future developments – neither science nor regulations are static.
16	Resources, official guidance, further reading and centres of expertise.	Reference sources for further information focussing on the technical resources.
Appendix A	Substance Classification and labelling under REACH.	The new CPL Regulations.
Appendix B	Further discussion of substance identification and sameness.	The importance of substance identification as a first technical step.
Appendix C	Tools for REACH compliance: IUCLID, Chesar and in-house databases.	Some practical advice for registrants.
Appendix D	Glossary	–

How Different Types of Reader Might Use This Book

The contents cover a wide range of needs. The following are suggestions for how to make the most of the content.

	Chapters
Strategy for REACH	1, 2, 3, 4, 11, 13–15
Substance assessment and registration	1, 4–10
Authorisation concerns	1, 13, 14
Substance substitution	12, 13

1

Introduction: Policy and Scientific Context of Chemicals Risk and Risk Management

This chapter acts as a foundation of understanding for the rest of the book. It introduces the regulatory systems that demand the evaluation of risk for chemical substances that are intended to be used and placed on the market. It sets out the development of risk assessment in the European, global and national contexts. This chapter also explains the key concepts of hazard and exposure. Hazard is defined as the inherent properties of a substance that may make it harmful – flammability, toxicity and so on. Exposure refers to the ways in which humans and the environment come into contact with substances. The reasons for bringing together hazard and exposure in order to understand risk are explained.

The focus of this book is the REACH Regulation (most often referred to just as ‘REACH’), as this is the main regulatory driver for the risk assessment of chemical substances in the European Union. REACH (**R**egistration, **E**valuation, **A**uthorisation & restriction of **C**hemicals), however, should be viewed in the context of other legislation that is either directly or indirectly connected to the REACH Regulation. With this in mind, the later sections of this chapter include consideration of United Kingdom legislation on chemicals, including worker and environmental protection. These sections are intended to serve as examples of how REACH is connected to prior legislation and how compliance with REACH works with such legislative regimes at national level.

The purpose of this book is to set out in a simple and concise way how to assess and manage the risks of chemicals to humans and the environment. This is done within the context of the main legislation that applies to the safety of the manufacture and use of chemicals in the European Union (EU) – the REACH Regulation. It is not the intention to give detailed guidance on each aspect of risk assessment or in depth assessment of specific aspects of REACH, but rather to explain the main aspects of chemical risk assessment and the processes that are applied, so that each aspect can be understood

within the context of REACH. This book should act as a handbook, so the reader/user can find out about specific aspects of the process and technical elements in sufficient detail to understand where and how they fit in the risk assessment of chemicals, and where to look for more detailed information.

Legislation on chemicals has specific purposes and is aimed at control of particular processes or aspects of the manufacture, use, reuse and disposal of chemicals. In addition, some legislation is aimed at chemicals that are used in a particular way (for example pharmaceuticals or pesticides), or because they have specific dangerous qualities (carcinogens, explosives and highly flammable substances), and some legislation is aimed at protection of specific sections of the population (e.g. workers, consumers, pregnant workers). Other legislation is aimed at environmental protection by specific control of releases to the environment (e.g. integrated pollution potential and control – IPPC) or monitoring specific parts of the environment (e.g. the Water Framework Directive – WFD for water). Inevitably there is overlap between all this legislation on chemicals, and today companies manufacturing and using chemicals have to be aware of a wide range of legislation to ensure that they are complying with all the relevant laws to operate legally and safely.

REACH is concerned with the safety of chemical substances for placement on the European market. REACH is a ‘Regulation’ (as compared to a Directive¹) meaning that REACH is a law that applies equally and with the same text in all EU Member States. REACH requires that industry supplies specific information on individual chemicals in order to demonstrate that its manufacture and specific uses in the EU market are safe² for humans and the environment.

Key features of REACH are:

- Those who make chemicals in the EU or import them into the EU (Manufacturers/Importers, i.e. ‘industry’) for placing on the EU and EEA (European Economic Area) market³ are responsible for supplying information to demonstrate safe manufacture and use.
- The safety assessments done by industry are based on a risk assessment that examines the properties of the substance that may make it dangerous to humans and/or the environment, and the way the chemical is used that causes humans and/or the environment to come into contact with it.
- Information supplied is assessed by a central regulator: the European Chemicals Agency (ECHA).
- Each substance is assessed for safety on its own merit: that is, the potential risks or impact of each chemical and its uses are assessed on their own and not in combination with other substances.⁴
- The safety of chemicals is assessed only for the uses that the manufacturer puts forward; thus the assessment is valid for these uses only.
- The safety of all parts of the chemical’s life cycle are relevant – from manufacture to final disposal (including recycling/reuse, if relevant).

¹ A Directive is applied (transcribed) by each Member State of the Union in its own law.

² What constitutes and is designated as ‘safe’ with the context of REACH is addressed in later chapters of this book.

³ There are specific rules for substances that are used for the purposes of research – these are identified later (Section 4.1 and Appendix C).

⁴ However, the breakdown products of the substance are relevant to the risk assessment.

- REACH is applied to the manufacture/import and use of chemicals substances, not chemicals that are used specifically as pharmaceuticals, biocides, plant protection products (pesticides), veterinary medicines and cosmetics. However, it does apply to the chemicals that are used to make these products.

The concepts that underpin the REACH Regulation are not new; what is new is the application of a single system for assessing the safety of chemicals being placed on the European market. To understand why REACH was created as a Regulation it is necessary to briefly look at what was in place prior to REACH coming into force in 2007.

The pre-REACH legislative framework comprised three main pieces of legislation, namely:

- Existing Substances Regulation (ESR).
- Dangerous Substances Directive (DSD) Seventh Amendment – concerning the placing on the market of ‘new’ substances (in the UK this was the Notification of New Substances Regulation or NONS). The legal basis was laid out in Directive 67/548/EEC.
- Marketing and Use (or ‘Limitations’) Directive.

In addition, the DSD set out the rules for the classification and labelling of substances. This is of key importance for hazard communication and also because the classification of substances leads to how the substance is dealt with in other legislation (Appendix A). This includes, importantly, how the substance should be handled and treated by users of the substance.⁵

Under this legislation prior to REACH, substances defined as ‘new’ (i.e. placed onto the European market after 1981) were required to be tested and notified before marketing in volumes above 10 kg. For higher volumes more in-depth testing – focused on long-term and chronic effects – had to be provided. On the basis of that information, the substances were assessed for their risks to human health and the environment. There were, however, no corresponding requirements for ‘existing chemicals’: chemicals that were on the European Community market between 1 January 1971 and 18 September 1981. These ‘existing chemicals’ were listed in the EINECS (European INventory of Existing Commercial chemical Substances), which consists of about 100 000 existing substances. This accounts for about 99% of the total volume of chemicals on the European market.

Risk assessment of new substances coming onto the market under pre-REACH legislation formed the basis of REACH and is the core of the registration of chemicals within REACH. For a new chemical to be placed on the EU market, the manufacturer had to chemically describe the substance and provide basic information on its properties in terms of hazard and use, and assess the potential risks to humans and the environment from the manufacture and use of the substance. The amount of information to be provided depended upon on the amount to be placed on the market. A manufacturer could present its information dossier to the ‘Competent Authorities’ of any of the Member States, who would assess the information and present a risk assessment of the substance and its uses for acceptance by all other Member States. The system was looked after

⁵ Note that the regime for the classification and labelling of chemical substances is explained in Appendix A.

at EU level by the European Chemicals Bureau (part of the European Commission's Directorate General Joint Research Centre – DG JRC). The assessment could reach one of four possible conclusions:

1. **No immediate concern:** no need to consider again before next tonnage trigger.
2. **Concern:** define further information needs and requests at next tonnage trigger.
3. **Concern:** define further information needs and seek immediately.
4. **Concern:** immediately make recommendations for risk reduction.

For the existing EINECS substances, the risk assessment of these was the responsibility of the regulators at European and Member State level. Substances were placed on priority lists, four of which were established with about 50 substances on each. The prioritisation by the European Community (EC) and Member States was based on hazard, uses and high tonnage use. For this limited subset of substances, each substance was appointed a Member State 'Rapporteur' with the responsibility of conducting the risk assessment, retrieving and assessing all relevant information, and presenting the risk assessment to a Member State and EC expert group with representation from relevant industry sector groups for discussion and agreement. The assessments often required further information from industry (at the industry's expense) but the assessments were done by the Rapporteur and by their own government scientists. The assessments could conclude with one of three possible options for each of the different uses of the chemical and the risks they present to humans working with or using the substances as consumers, and each part ('compartment') of the environment (i.e. freshwater, marine, soil, air, and sewage treatment works). The three available conclusions were:

1. Need for further information and/or testing.
2. At present no need for further information and/or testing and no need for risk reduction measures.
3. Need for limiting the risk.

While the system for assessing new substances was generally regarded to work well and efficiently, the system for existing substances was slow (albeit thorough) and came under increasing criticism. This was both from industry, who wanted to show that their substances were risk assessed as safe, and pressure groups, who wanted to see the existing substances assessed and risky uses banned.

The solution was REACH, in which all substances new and existing are treated the same way, and the burden of information provision is on those who are placing the products on the market. Existing substances are brought into REACH as 'phase-in' substances; the timing for registration of these substances is based on particular hazard and the volume placed on the market. Former 'new' substances are considered to be registered within REACH, but the registrations must be updated before the next tonnage band is reached.

1.1 Overview of the Risk Assessment of Chemical Substances

This section describes the main concepts that underpin risk assessment of chemicals (although these concepts also underpin many other assessments of risk). The assessment