PETER FISK ASSOCIATES LTD

Chemical Risk Assessment

A Manual for REACH

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Peter Fisk Associates Ltd

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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.
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

Chapter 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 **Ch**emicals), 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