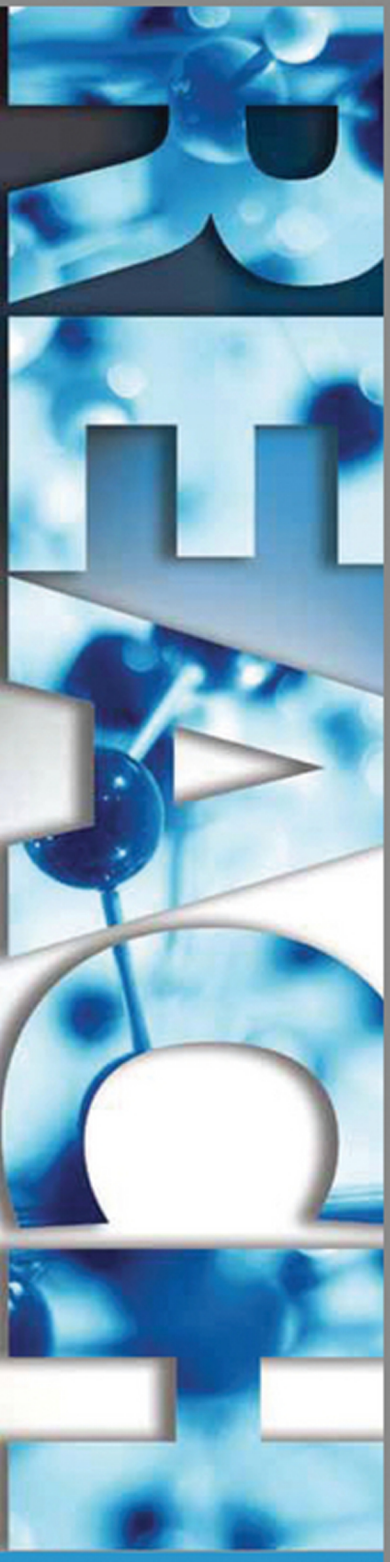
PETER FISK ASSOCIATES LTD

Chemical Risk Assessment

A Manual for REACH



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Chemical Risk Assessment: A Manual for REACH

Peter Fisk Associates Ltd

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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 **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

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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 Directive[1]) 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 safe[2] 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) market[3] 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