Contents

Foreword *XIII*
Preface *XV*

1 Introduction *1*
1.1 History *1*
1.2 The REACH Regulation – A Short Overview on the Table of Contents *3*
1.3 Purpose and Scope of REACH *4*
1.4 Other Regulations and Directives that are Important in the Context of REACH *7*
1.4.1 Fees and Charges Payable to the European Chemicals Agency *8*
1.4.2 Competition Law *9*
1.4.3 GHS and CLP *10*
1.4.4 Other Regulations Containing the Wording REACH *11*
References *11*

2 Roles under REACH *15*
2.1 Manufacturer within the EU *15*
2.2 Non-EU Manufacturer, Importer and Only Representative *16*
2.3 Downstream User *20*
2.4 Trader within EU versus Non-EU Trader and Distributor *23*
2.5 Examples and Exercises *25*
References *26*

3 What Sort of Substances have to be Considered under REACH *27*
3.1 Substance, Mixture and Article under REACH *27*
3.2 Different Compositions *28*
3.2.1 Mono-constituent Substance *28*
3.2.2 Multi-constituent Substance *28*
3.2.3 Substances of Unknown or Variable Composition, Complex Reaction Products or Biological Materials *29*
3.3 Different Types of Use *29*

3.3.1 Substance with End Use *29*
3.3.2 Intermediate *30*
3.3.2.1 Non-isolated Intermediate *30*
3.3.2.2 On-site Isolated Intermediate *30*
3.3.2.3 Transported Isolated Intermediate *31*
3.4 Phase-In Substances *31*
3.5 No-Longer Polymers *32*
3.6 Non-Phase-In Substances *32*
3.7 Substances that Already Have Been Notified *33*
3.8 Overview on Official EC Numbers and not Official List Numbers *33*
3.9 Exemptions from REACH *34*
3.9.1 Non-isolated Intermediates *35*
3.9.2 Substances Manufactured or Imported in Amounts below 1 t/a *35*
3.9.3 Substances Mentioned in Annex IV *35*
3.9.4 Substances Listed in Annex V *36*
3.9.5 Substances in the Interest of Defense *36*
3.9.6 Waste and Recovered Substances *37*
3.9.7 Polymers *37*
3.9.8 Re-imported Substances *39*
3.9.9 Further Exemptions: Use in Medicinal Products or for Food and Feedingstuffs *39*
3.9.10 Product and Process Orientated Research and Development *40*
3.9.11 Substances Regarded as Being Registered *40*
3.9.12 How to Cope with Situations in Which Parts of the Manufactured Amount are Falling under REACH and Another Part is Exempted *42*
3.10 Check-List for Business Managers *43*
3.11 Examples and Exercises *44*
References *47*

4 Obligation to Submit a Registration Dossier *49*
4.1 Who has to Register? Who may Register? *49*
4.2 Pre-registration and Late Pre-registration *53*
4.3 When Does a Substance have to be Registered? *55*
4.4 Special Rules for Non-EU Manufacturers *56*
4.5 Consequences for Globally Acting Enterprises/What to Take into Account within a Decision-Making Process? *59*
4.6 Examples and Exercises *59*
References *60*

5 Types of Registration *61*
5.1 Standard Registration, Full Registration or Registration as a Substance *70*
5.2 Registration as an On-site Isolated Intermediate *70*
5.3 Registration as a Transported Isolated Intermediate *71*
5.4 Formerly Notified Substances *80*

5.5 PPORD *80*
5.6 Examples and Exercises *80*
References *81*

6 Data Requirements and Dossier Preparation *83*
6.1 Data Requirements *83*
6.2 Dossier Preparation *84*
6.2.1 PPORD *89*
6.2.2 Inquiry Dossier *90*
6.2.3 On-site Isolated Intermediate *91*
6.2.4 Transported Isolated Intermediate *93*
6.2.4.1 Check-List for Preparation of the Substance Data Set in IUCLID5 *95*
6.2.5 Standard Registration (Full Registration) *95*
6.3 Some Useful Tips for Entering Data and Information in Certain Chapters in IUCLID5.4 *98*
6.3.1 IUCLID Section 1.2 *98*
6.3.2 IUCLID Section 1.3 *99*
6.3.3 IUCLID Section 1.4 *100*
6.3.4 IUCLID Section 1.7 *101*
6.3.5 IUCLID Section 2.3 *101*
6.3.6 IUCLID Section 3.1 *102*
6.3.7 IUCLID Chapter 11 *102*
6.3.8 IUCLID Chapter 13 *103*
6.4 Data Requirements, Type of Registration and Costs/Fees *103*
6.5 Examples and Exercises *105*
References *105*

7 Claiming a Registration Number for Already Notified Substances *107*
7.1 Formerly Notified Substances are Regarded as Registered under REACH *107*
7.2 How to Claim the Registration Number Under REACH for a Formerly Notified Substance *108*
7.3 When to Update a Registration Dossier of a Formerly Notified Substance and How to Do It *109*
7.4 Examples and Exercises *109*
References *110*

8 Process for Registration of Non-Phase-In Substances *111*
8.1 Inquiry Dossier *112*
8.2 Preparation of the Registration Dossier *113*
8.2.1 Registration as Member of Joint Submission *115*
8.2.2 Registration within a Joint Submission in Cooperation with Other Potential Registrant(s) *115*

8.2.3 Single Submission *116*
8.3 Difficulties and Problems that can Arise in the Context of the Registration of Non-Phase-In Substances *117*
8.4 Examples and Exercises *118*
References *119*

9 Process for Registration of Phase-In Substances *121*
9.1 Preparing for Pre-registration and Late Pre-registration *121*
9.2 Communication within Pre-SIEF *124*
9.2.1 Data Holders *125*
9.2.2 Third Party Representatives *126*
9.2.3 Potential Registrants *126*
9.2.4 Duties and Rights of the Different SIEF Participants *126*
9.3 Formation of SIEF *127*
9.3.1 Substance Sameness and Substance Identification Profile (SIP) *130*
9.3.2 Lead Registrant Agreement *131*
9.3.3 Lead Registrant Notification *134*
9.4 Cooperation within the SIEF *134*
9.4.1 Obligations of SIEF Participants *135*
9.5 Data Sharing *135*
9.5.1 Consortium Agreement *137*
9.5.2 Cooperation Agreement *137*
9.5.3 SIEF Agreement *137*
9.5.4 Letter of Access *137*
9.5.4.1 Letter of Access Concerning Data as Studies and Tests *138*
9.5.4.2 Letter of Access to a Registration Dossier *139*
9.6 Data Sharing Disputes *140*
9.7 Opt-Out *142*
9.8 Registration Dossier of the Lead Company and Registration Dossiers of the Members of Joint Submission *144*
9.9 Overview on Important Steps within the Process for Registration of Phase-In Substances *145*
9.10 Examples and Exercises *145*
References *146*

10 What Happens after Submission of Your Registration Dossier to ECHA? *147*
10.1 Initial Verification *147*
10.2 Overall Completeness Check *149*
10.3 Receiving the Reference Number *150*
10.4 End of Pipeline Activities *150*
10.5 Dossier and Substance Evaluation *152*
10.5.1 Examination of Testing Proposals *152*
10.5.2 Compliance Check of Registration *153*
10.5.3 Substance Evaluation *154*

10.5.4 On-site Isolated Intermediates are not the Object of Evaluation *155*
10.6 Further Obligations of the Registrant and Downstream Users *155*
10.6.1 Safety Data Sheets and extended Safety Data Sheets *155*
10.6.2 Documentation of Correspondence with Customers Purchasing Transported Isolated Intermediates *157*
10.6.3 Substance Volume Tracking *157*
10.6.4 Obligation to Update Information *158*
10.6.5 Obligations of Downstream Users *158*
10.7 Examples and Exercises *159*
References *160*

11 Update of the Registration Dossier *163*
11.1 When to Update Your Registration Dossier *163*
11.2 Requested Updates *164*
11.2.1 Update Requested Because of Missing Information *164*
11.2.2 Updates Requested as a Result of Dossier Evaluation *165*
11.2.2.1 Update Requested as a Result of a Compliance Check *165*
11.2.2.2 Update Requested after Examination of Testing Proposals *166*
11.3 Spontaneous Updates *166*
11.3.1 Update Because of Change in Status or Identity of the Registrant *167*
11.3.2 Update Because of Change in the Composition of the Substance *168*
11.3.3 Update Because of Change of Tonnage Band *169*
11.3.4 Update Because of New Identified Uses *169*
11.3.5 Update Because of New Knowledge of the Risks of the Substance *170*
11.3.6 Update Because of Any Change in Classification and Labeling *170*
11.3.7 Update Because of an Amendment in the Chemical Safety Report *171*
11.3.8 Update Because of the Need to Perform Further Tests *171*
11.3.9 Update Because of a Change in the Access Granted to Information in the Registration *171*
11.4 Update of Dossiers of Formerly Notified Substances *172*
11.4.1 Update Because of Tonnage Band Increase for Former Notified Substances *172*
11.4.2 Other Updates for Former Notified Substances *173*
11.4.3 Confidentiality Claims that were Previously Done in the Notification *173*
11.5 Update of Dossiers for PPORD Notifications *174*
11.6 Costs Concerning Updates *175*
11.7 Examples and Exercises *176*
References *178*

12 Substances of Very High Concern and Authorization Process *181*
12.1 Uses that are Exempted from Authorization *181*
12.2 Substances of Very High Concern (SVHC) *182*

12.3 Substance Identification and Identification Procedure *184*
12.3.1 Identification Procedure *185*
12.3.2 Content of an Annex XV Dossier *185*
12.3.2.1 Annex XV Report for the Identification of a Substance as a CMR, PBT, vPvB or ELOC *187*
12.4 Inclusion of a Substance in the Candidate List of Substances of Very High Concern (SVHC) *187*
12.5 Prioritization and Inclusion of Certain SVHCs in Annex XIV *188*
12.6 Information in Annex XIV *188*
12.7 Restrictions and Information in Annex XVII *189*
12.8 Application for Authorization *190*
12.8.1 Main Elements of an Application for Authorization *191*
12.8.1.1 Adequate Control Route *194*
12.8.1.2 Socio-economic Assessment (SEA) Route *196*
12.9 Data Requirements and Documents Needed for an Application for Authorization *196*
12.9.1 Substance Identity and Composition Concerning IUCLID Sections 1.1 and 1.2 *197*
12.9.2 Identifiers to be Entered in IUCLID Section 1.3 *198*
12.9.3 Identification of the "Uses Applied for" Concerning IUCLID Section 3.5 *198*
12.9.4 Assessment Reports Concerning IUCLID Chapter 13 *199*
12.9.5 Information to be Provided in the Dossier Header *199*
12.10 Submission of the Application of Authorization, Deadlines and Fees *200*
12.11 Subsequent Applicants and Their Obligations *201*
12.12 Process after Submission of the Application for Authorization *201*
12.12.1 Requested Update *202*
12.12.2 Spontaneous Update *202*
12.12.3 To Dos after Granting of an Authorization *202*
12.12.4 To Dos after Refusal of an Authorization *202*
12.12.5 Review of Authorizations *203*
12.13 Examples and Exercises *203*
References *204*

13 Achieving REACH Compliance within Your Company – How to Implement Processes to Ensure Legal Compliance *207*
13.1 List of Used Raw Materials *207*
13.1.1 Define Your Role under REACH *208*
13.1.2 Define the Registration Deadline Based on Properties *211*
13.1.3 Identify Uses of a Certain Substance within Your Company *211*
13.1.4 List of Raw Materials when Our Company is a Downstream User *214*
13.1.5 Process after Receiving a SDS or an eSDS from Your Supplier *216*

13.1.5.1 Four Key Steps in Checking Safety Data Sheets and Exposure Scenarios *216*
13.1.5.2 Information to be Forwarded to Customers down the Supply Chain *216*
13.2 List of Substances that are Manufactured in Your Company *217*
13.2.1 Identification of Registration Obligations *218*
13.2.2 Define the Registration Deadline for Substances Manufactured within Your Company Based on Their Properties and Consider Consequences if a Substance is Included in the SVHC Candidate List *218*
13.2.3 Uses at the Company's Own Site and Identified Uses of the Customers *221*
13.3 Documentation Concerning Manufacturing Process of OIIs and TIIs and Documentation of the Correct Use of TIIs by Customers *224*
13.3.1 In-house Documentation *224*
13.3.2 Confirmation from Downstream Users Concerning Art. 18(4) and Further Exemptions *224*
13.4 Substance Volume Tracking *225*
13.4.1 Substance Volume Tracking for EU Manufacturer *225*
13.4.2 Substance Volume Tracking for a Non-EU Manufacturer *225*
13.5 Examples and Exercises *228*
References *228*

14 Communication in the Supply Chain *229*
14.1 Communication Obligations According to the REACH Regulation *229*
14.2 Communication to be Done by Suppliers *231*
14.2.1 Communication from Supplier to EU Customers *231*
14.2.2 Communication from Supplier to Non-EU Customers *232*
14.2.3 Information for Workers *233*
14.2.4 Communication with Upstream Supplier *234*
14.2.5 Communication with Authorities *234*
14.2.6 Further Communication Obligations for Suppliers in the Context of Authorisation *235*
14.3 Communication to be Done by Non-EU Manufacturers *235*
14.3.1 Communication from Non-EU Manufacturer to his Only Representative *236*
14.3.2 Communication from Non-EU Manufacturer to EU Customer *236*
14.3.3 Communication from Non-EU Manufacturer to Non-EU Customers *236*
14.3.4 Communication from Non-EU Manufacturers to Their Suppliers *241*
14.4 Communication to be Done by Non-EU Distributors or Non-EU Traders *243*
14.4.1 Communication with EU Customers *244*

14.4.2 Communication with Non-EU Manufacturers *245*
14.4.3 Communication with Only Representative Acting on behalf of a Non-EU Manufacturer (Supplier) *246*
14.5 Communication to be Done by a Downstream User or a Downstream Supplier *247*
14.5.1 Communication with Suppliers *247*
14.5.2 Communication with Only Representative of Non-EU Manufacturer *248*
14.5.3 Communication with Customers (Downstream Users) *248*
14.5.4 Communication from Downstream User with Workers *249*
14.5.5 Communication from Downstream User to Authorities *249*
14.6 Communication to be Done by an Only Representative *249*
14.6.1 Communication with Non-EU Manufacturer *250*
14.6.2 Communication with ECHA and National Authorities *250*
14.6.3 Communication with Customers of the Non-EU Manufacturer *250*
14.7 Examples and Exercises *253*
References *254*

Appendix – Answers and Solutions Concerning the Sections Examples and Exercises within this Book *255*
Index *281*