

Herbert F. Bender, Philipp Eisenbarth

# Hazardous Chemicals

Control and Regulation in the European Market



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Control and Regulation in the European Market



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**Hazardous Chemicals**

## 1807–2007 Knowledge for Generations

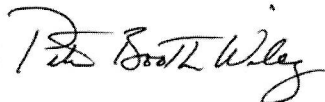
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## Preface

During the production and use of products in many industries and sectors, it is often necessary to use a variety of chemical ingredients each of which might possess hazardous properties. Hence, a knowledge of the intrinsic properties of such substances – and the resultant risks that might be encountered in the workplace – is an essential prerequisite, not only for avoiding occupational risks but also for installing the correct safety measures and fulfilling all legal requirements. Whilst a limited knowledge of these intrinsic properties may lead to an overestimation of the harmful effects of well-known hazardous chemicals, much greater risks of daily life – for example, the smoking of cigarettes – may often be underestimated or even ignored. Clearly, without any knowledge of the real risks that might be encountered, adequate protective measures cannot be undertaken.

Consequently, the first section of this book contains a comprehensive description of the properties of substances, following the guidelines of the European Union for classifying chemicals as “hazardous”. In industry, trade and commerce, “preparations” are generally used much more often than “substances”; hence, the basic rules for classifying preparations are of special importance in everyday life, and not only in the chemical industry and its related divisions.

In terms of occupational safety, a major part of this handbook comprises a detailed description of the requirements and the wide range of possible safety measures available. Although the use of personal protective equipment does not play a primary role, its importance in everyday working life justifies a comprehensive description.

Very often, engineers, natural scientists or operational supervisors find it difficult to remain totally familiar with all of their legal duties and responsibilities. Often, the countless regulations with which they must conform are deemed by them to be unmanageable, incomprehensible and, in many cases, not applicable. Yet, a civilized, industrialized society expects its industries and economies to comply with all legal requirements. Consequently – and as far as possible – this book attempts to provide an overview of responsibilities emanating from the major chemical regulations and directives of the European Union.

In order to present a pragmatic, workable approach to the different legal requirements, it would be impossible to provide a detailed description of every regulation. However, during many years’ experience in managing hazardous sub-

stances in the chemical industry, the most frequently recognized shortfalls are caused by an ignorance of existing legislation and – perhaps less often – by their incorrect appliance. Thus, the primary aim of this book was to provide a comprehensible overview rather than a complete presentation of all specialties. If necessary, of course – and in special cases – the reader should consult directly the cited regulations or directives.

Unlike the individual legislative demands required for the pre-marketing classification and labeling of materials, today the transport of hazardous goods is the subject of international harmony. Moreover, because of the dominant role of road transport, the basic rules of the AD-regulations for different classes and categories are described in detail.

According to the latest decision of the European Institutions, the Global Harmonized System (GHS) will be implemented in the European Community within the next few years, and the main principles of this are presented in Section 7.3. This introduction to the classification and labeling system, which in future will be enforced worldwide and not only in the European Union, provides a simple overview of this complicated and sophisticated construct.

On the basis of the so-called *White Book for a New Chemical Legislation*, the European Union some years ago launched the REACH initiative. This is shortly to undergo a second reading in the European Parliament, and no major changes are expected for the final regulations. However, as REACH comprises more than 1000 pages (including various annexes), there is insufficient space in this book to describe the legislation precisely in all detail. In fact, most of the REACH Implementation Processes (RIPs) are ongoing, such that the resultant Technical Guidance Documents (TGDs) have not yet been finalized. Nonetheless, this important paradigm exchange will in future dominate all legislation within the chemical industry, and a short description of the basic principles of REACH should not be excluded.

The authors wish to express their gratitude to the countless colleagues and friends without whose valuable discussions and stimulation this book could not have been written. Likewise, many valuable suggestions from numerous national and European working groups have proved to be vitally important by providing a broad understanding of the different needs.

And last – but not least – we thank our wives and families for their patience and understanding support, which was essential during the time-consuming creation of this volume.

Ludwigshafen, October 2006

Herbert F. Bender  
Philipp Eisenbarth

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## 1

## Regulations of the European Union Concerning Chemicals

## 1.1

### The European Institutions

The legal system of the European Union is very complex and comprehensive, consisting of regulations, directives, decisions, recommendations, resolutions, and memoranda.

The European Union consists of the following institutions:

- European Parliament
- Council of the European Union – Presidency
- European Commission
- Court of Justice of the European Communities
- European Court of Auditors
- European Ombudsman
- European Data Protection Supervisor

The **European Parliament** consists of 732 Members, elected by the different member states. The daily work takes place mainly in 24 committees. Of special interest for the legislation on chemicals are the environmental, the employment, and the industry committees.

The **European Council** is the supreme authority and central decision-making body of the European Union. As it consists of the Heads of State or Government and the President of the European Commission, it embodies the highest political authority of the Member States and of the European Community. The European Council comprises the Heads of State or Government and the President of the European Commission, who are assisted by the Ministers for Foreign Affairs of the Member States and a member of the European Commission. The European Council meets four times a year, and is chaired by the Head of State or Government of the Member State holding the Council Presidency at the time. Additional meetings may be scheduled in special circumstances.

The **Commission** is responsible for defending the general interests of the EU, and for ensuring that EU law is both observed and further developed where necessary.

The Commission has a strong position in the law-making process. Its right of initiative or exclusive right to propose legislation means that, in matters relating

to the European Community, the Council can generally act only on the basis of a Commission proposal, although it can call on the Commission to present proposals. The Commission also has considerable scope to shape policies further downstream in the legislative process.

The Commission shares the right of initiative in the common foreign and security policy and in police and judicial cooperation in criminal matters with the Member States, and its role in the further course of the legislative process in these areas is also weaker.

The Commission is also responsible for monitoring the application of Community law. In this capacity, it can bring infringement proceedings against Member States before the European Court of Justice.

The Commission is the institution primarily responsible for implementing Community law and it is exclusively responsible for executing the Community budget.

The Commission “College” or body of Commissioners has 25 members (one for each Member State), who are required to be completely independent of their governments in the exercise of their functions and whose term of office is 5 years. The entire Commission has to be confirmed by the European Parliament, which also has the power to dismiss the former by a vote of no confidence.

The President of the European Commission has a particularly important political role, as the President represents the Commission to the outside world and is also a full member of the European Council.

The Commission as the body of Commissioners must be distinguished from the administrative structure underpinning it, which is made up of several Directorates-General and Services.

The Commission are responsible for the following areas:

- Agriculture
- Audiovisual and Media
- Biotechnology
- Civil Society
- Competition
- Consumers
- Culture
- Customs Union
- Economic and Monetary Union
- Education and Training
- Employment and Social Affairs
- Energy
- Enterprise and Industry
- Environment
- Fisheries and Maritime Affairs
- Food Safety
- Freedom, Security, and Justice
- Information Society

- Internal Market
- Public Health
- Regional Policy
- Research, Development, Technology, and Innovation
- Space
- Sport
- Taxation
- Trans-European Networks
- Transport
- Youth
- International Affairs
- Institutional Affairs
- Finance

The **Court of Justice** has the important task of monitoring the legality of actions by the Community institutions and providing legal protection. The application of Community law by the Member States is also subject to the independent judicial scrutiny of the European Court of Justice. In addition, the Court gives the national courts guidance on the interpretation of the EC Treaty and Community legal acts. It also has exclusive jurisdiction in disputes between Member States concerning the interpretation and application of Community law. The court does not have jurisdiction in matters concerning the Common Foreign and Security Policy, but it acquired limited powers in police and judicial cooperation in criminal matters under the Amsterdam Treaty.

The Court has exclusive jurisdiction in actions of fundamental importance, e.g., Treaty infringement proceedings against Member States or disputes between Union institutions, and currently also in references for preliminary rulings from the national courts.

## 1.2

### European Legislation

All legal requirements of the European Union are based on the Treaty of the European Union. The Treaty was adopted by the council of ministers.

In the European Union, two different types of legislation exist:

- Regulations
- Directives

**Regulations** are valid in all member states immediately, adoption following national procedures not being necessary. In the area of chemicals there are much fewer Regulations than Directives. Important examples are the Regulation for existing chemicals 793/93/EC [1-1], the Regulation for import and export of dangerous chemicals 304/2003/EC [1-2], and the biocide product Regulation 1896/2000/EC [1-3]. A very popular example will be the REACH legislation, which will be the

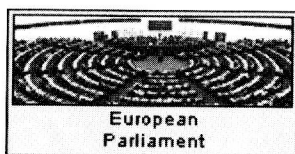




European Union's supreme political body



Is sometimes referred to as the motor of the European Union and the guardian of the Treaties



Directly elected assembly representing the citizens of the European Union's Member States



Represents Member States' interests in the European Union



Fig. 1.1 The institutions of the European Union.