

## 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.

important new chemical legislation of the European Union. For more details, see Chapter 8.

In contrast, the EC **Directives** are first submitted to the Member States and have to be implemented in national legislation. The time period for implementation by the Member States is fixed individually in every Directive. In practice, many Member States do not meet this obligation in time. The EU Commission is allowed to punish by demanding a fine, which has happened in several cases in recent years.

An increasingly important issue is the relevance of directives in cases where the transmission time is over but no incorporation in national legislation has occurred. As a consequence of the latest decision of the Court of Justice, individuals can personally oblige member states to adopt a Directive if this is deemed to be beneficial.

Two different types of Directives have to be distinguished. Directives can be issued on the basis of article 95 or article 136 of the EC Treaty.

Legislation regulating the free market of products is based on **article 95** and essentially cannot be changed. The member States are only allowed to transfer the wording into their national laws without changing the legislation. Typical examples are the Dangerous Substance Directive 67/548/EEC [1-4], the Dangerous Preparation Directive 1999/45/EC [1-5], the Safety Data Sheet Directive 91/155/EEC [1-6], and the Restriction Directive 76/769/EEC [1-7].

Directives dealing with the issues of occupational safety and health are based on **article 137** of the Treaty and define, in contrast to the first mentioned Directives, only the minimum standard. National legislation is allowed to require additional obligations. Representative examples are the agent directive 98/24/EC [1-8] and the carcinogen directive 2004/37/EC [1-9].

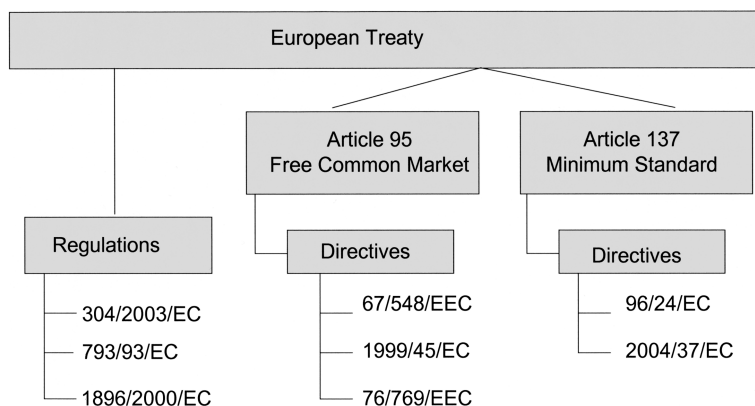
Aside from the Regulations and Directives are the **Guidelines**. These are established for practical help in the implementation of the Directives and Regulations. Guidelines are exclusively addressed to the Member States and should be transferred, if the necessity exists, into national, non-binding legislation.

In the field of chemicals and substances, only a few Guidelines exist. For example, in 2005 a Guideline was adopted under the umbrella of the Chemical Agent Directive 98/24/EC [1-8].

Figure 1.2 gives an overview to the different types of legislation of the European Union.

### 1.3 Definitions

**Substances** means chemical elements and their compounds in their natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.



**Fig. 1.2** Structure of the European Legislation.

**Preparation** means a mixture or solution composed of two or more substances.

An **article** is a product which has a special shape, configuration, or surface which determines its use more than its chemical components.

**Placing on the market** means making a product available to third parties. Importation into the Community customs territory is deemed to be placing on the market.

**Classification** is the allocation to one of the hazardous properties.

**EINECS** (European Inventory of Existing Chemicals) means the European Inventory of Existing Commercial Substances. This inventory contains the definitive list of all substances deemed to be on the Community market on 18 September 1981.

**ELINCS** (European List of New Chemical Substances) is the European List of Notified Chemical Substances. These are all the substances notified under the legislation of Directive 67/548/EEC.

**Notification** means the documents, with the requisite information, presented to the competent authority of a Member State.

## References

- [1-1] Council Regulation 793/93/EEC, OJ L 84/1 of 23 March 1993.
- [1-2] Regulation 304/2003/EC, OJ L 63, 06/03/2003, p. 1.
- [1-3] Council Regulation 1896/2000/EC, OJ 228 of 08/09/2000, p. 6.
- [1-4] Council Directive 67/548/EEC OJ L 196, 16/08/1967, p. 1.
- [1-5] Council Directive 1999/45/EC, OJ L 200, 30/07/1999, p. 1.
- [1-6] Commission Directive 91/155/EEC, OJ L 76, 22/03/1991, p. 35, last adopted by Commission Directive 2001/58/EC, OJ L 212, 7/8/2001, p. 24.
- [1-7] Council Directive 76/769/EEC, L 262, 27/9/1976, p. 201.
- [1-8] Council Directive 98/24/EC, OJ L 131, 05/05/1998, p. 11.
- [1-9] Council Directive 2004/37/EC, OJ L 229, 29.06.2004, p. 23.