

### **EU Law Making Process**

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### 1. The European Union

The origins of the European Union trace back to the 1957 Treaty of Rome, which created the then European Economic Community (EEC). The Treaty of Rome was primarily concerned with stimulating economic growth by creating a common market for the movement of goods, people and services between the member states.

The European Union now has greatly extended political, economic and legislative powers built around the 'institutional triangle' of the Commission, Council and Parliament that comprises many institutions and agencies.

These three institutions i.e. the Commission, Council and Parliament make up the legislative and executive power of the European Union responsible for policy making.

## 2. The European Commission

The European Commission is the Executive Body, responsible for initiating and implementing legislation, as well as budgets and programmes adopted by Parliament and the Council.

The Commission also ensures that Community law is properly applied, alongside the Court of Justice, and represents the Union on the international stage, negotiating international agreements in trade and cooperation.

### 3. The European Council

The European Council comprises the heads of state or government of the 27 EU member states, the European Council President and the President of the European Commission. It is the main decision-making body and shares budgetary authority with the EU Parliament, as well as undertaking the following roles:

- Coordinates the economic policies of the member states, also developing foreign and security policy;
- Agrees international policy with other states or international organisations;
- Coordinates the activities of member states and adopts measures covering policing and judicial cooperation.



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## 4. The European Parliament

The European Parliament is directly elected every five years and has three main functions:

- 1. Shares legislative powers with the Council to adopt European law (directives, regulations, decisions), ensuring the democratic legitimacy of adopted texts.
- 2. Shares budgetary authority with the Council and can therefore influence EU spending.
- 3. Exercises democratic supervision over the Commission, approving the nomination of Commissioners and has the right to censure. It also exercises political supervision over all the institutions.

### 5. The European Chemicals Agency (ECHA)

The European Chemicals Agency was established with the REACH Regulation and is now responsible for managing the technical and administrative aspects of several areas of chemical legislation.

The European Chemicals Agency comprises the following:

A Management Board that is responsible for adopting the financial planning, the work programme and annual reporting of the Agency;

An Executive Director reporting to the Management Board that is responsible for the day to day management and administration of the Agency;

A Member State Committee, put in place to resolve differences of opinion on draft decisions proposed by the Agency or Member States, and to make proposals for the identification of substances of very high concern;

A Risk Assessment Committee, which prepares opinions following the evaluation of substances, restriction proposals, harmonised classification and labelling proposals and applications for authorisation;

A Committee for Socio-economic Analysis, which prepares opinions on applications for authorisation, on proposals for restrictions, and on questions relating to the socio-economic impact of proposed legislative action;

An **Enforcement Forum** to coordinate a network of Member State competent authorities responsible for enforcement;

A Biocidal Products Committee, which is responsible for preparing opinions on applications for the approval and renewal of active substances, identification of active substances that are candidates for substitution, applications for inclusion in Annex I of the Biocidal Products Regulation; applications for Union authorisation, and scientific/technical matters concerning mutual recognition;

A **Secretariat**, under the leadership of the Executive Director, to support the Committees and Forum, and to undertake work on registration and evaluation processes, as well as the preparation of guidance, maintenance of databases and provision of information;

A Board of Appeal, to decide on appeals against decisions taken by the Agency.

Organisation - ECHA (europa.eu)



### 6. European Commission Directorates-General

The different departments responsible for specific policy areas within the Commission are called Directorates-General (DGs).

The following DGs are responsible for chemicals legislation or tasks that ECHA implements:

- ❖ The Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs\* (DG GROW) is the main partner DG of ECHA. DG GROW is responsible for the REACH and CLP regulations, alongside the Directorate-General for Environment (DG ENV).
  - DG GROW is responsible for budgetary and administrative matters related to ECHA, as well as the EU Observatory for Nanomaterials (EUON) and the EU Chemicals Legislation Finder (EUCLEF).
- DG ENV is responsible for the REACH and CLP regulations together with DG GROW, as noted above. In addition, DG ENV is responsible for the Prior Informed Consent (PIC) and Persistent Organic Pollutants (POPs) regulations, and the Waste Framework and Drinking Water directives.
  - DG ENV leads EU activity on international chemicals policy, such as OECD\*\* cooperation, the Stockholm and Rotterdam conventions, and in relation to the Strategic Approach to International Chemicals Management (SAICM).
- The Directorate-General for Health and Food Safety (DG SANTE) is in charge of biocides legislation and a number of scientific issues, such as criteria for endocrine disruptors.
- The Directorate-General for Employment, Social Affairs & Inclusion (DG EMPL) is responsible for the Chemical Agents and Carcinogens and Mutagens directives, related to worker protection.
- The Directorate-General for Research and Innovation (DG RTD) manages research programmes that ECHA participates in, for example, the Partnership for the Assessment of Risks from Chemicals (PARC).

ECHA also cooperates closely with the Commission's Joint Research Centre (JRC) on scientific topics, such as developing and validating alternatives to animal testing, the risk assessment of nanomaterials and the Review Programme on the risk assessment of biocides.

\*SMEs: Small and medium enterprises

### 7. Law Making, the Treaties

The EU' Treaties give authority to the institutions of the Union in law making. There are two main treaties:

#### Treaty on the Functioning of the European Union (TFEU)

Most EU regulations and directives affecting chemical hazards are made under one or other of the articles of this Treaty. This is why the regulations and directives include the letters 'EU', or 'EC' if made under former Treaties establishing the Europeans Community (TEC), or the 'European Economic Community' (EEC).

#### Treaty on the Functioning of the European Union (TEU)

This deals mainly with political and monetary union.

<sup>\*\*</sup>OECD: Organisation for Economic Co-operation and Development



http://eur-lex.europa.eu/collection/eu-law/treaties.html.

### 8. Ordinary Legislative Procedure

The Ordinary Legislative Procedure is used for introducing primary legislative into Statute. It was formerly known as the co-decision procedure.

The Commission is responsible for setting out legislative proposals and in doing so is required to assess the potential economic, social and environmental impacts for the preparation of an impact assessment. The impact assessment should identify the key benefits and disadvantages for the policy option. Individuals, businesses and organisations are able to provide feedback on the proposed legislation through public consultation.

The legislative proposal is subject to scrutiny by both the Parliament and the Council, the first step of which is termed a **First Reading**.

The **European Parliament** examines the Commission proposal and may decide to adopt the Act if in agreement, or otherwise introduce amendments.

The Council may agree with the position from Parliament, or in the case that the Council believes that amendments are required, a **Second Reading** takes place.

There is no time limit on the first reading at the Parliament and at the Council

The Commission is empowered to withdraw a proposal if the Commission considers that the amendments excessively change the proposal.

During the second reading, the Parliament examines the Council position and may react as follows:

- Approve the Act, which is then is adopted
- Reject the Act, which will then not enter into force and the whole procedure ends
- Proposes amendments and returns the proposal to Council for a second reading

The Council then examines the second reading position from Parliament and may approve the amendments proposed by Parliament and the Act is adopted.

The timeframe is three months for each institution, with a possible extension of one month.

### Conciliation Committee

If agreement has not been achieved from a second reading and the legislative proposal has not been rejected, a **Conciliation Committee** is set up to try to find a solution, composing of an equal number of members of the Parliament and Council representatives.

If the Conciliation Committee is unable to agree on a text that would be acceptable to both institutions, the legislative act is not adopted, and the procedure is ended. However, if a joint text is agreed, it is forwarded to the Parliament and Council for a **Third Reading**.

The conciliation committee must be convened within 6 weeks, with a possible extension to 8 weeks. The committee then has 6 weeks to agree on a joint text.



If an agreement is reached, the wording of the joint text cannot be changed by either institution.

The Act is approved if the Parliament approves the text by a simple majority of votes cast, and the Council approves the joint text by qualitied majority.

Both the Parliament and the Council must act within 6 weeks from the date on which the joint text was approved.

The Agreed text of the legislative act published in the EU's Official Journal: <u>Access the Official Journal - EUR-</u> Lex (europa.eu)

### 9. Delegated Acts Procedure

The delegated acts procedure is in place for the Commission to establish measures of a technical nature to supplement or amend a legislative act, by way of introducing secondary legislation. The delegated act cannot alter essential elements of the primary legislation.

The proposal for the delegated act is drafted by the Commission, after consultation with experts from member state committees. Simultaneous transmission of the draft act, as well as other relevant documents are forwarded to the European Parliament and the Council for consideration. A public consultation on the draft text of a delegated act is usually opened for a four-week period.

There is a two-month review period in which objections can be raised by Parliament and/or Council, which may be extended by a further two months. However, if no objection is raised, the delegated act will be published in the Official Journal and enter into force on the twentieth day following its publication.

### 10. Categories of European Law

There are three 'categories' of European law that are binding:

- 1. **Regulations** Regulations apply directly and ensure uniform application throughout the Union. They are binding on Member States and do not require national transposition. Regulations do, however, require legislation to specify the applicable Competent and Enforcement Authority(ies), and to set penalties for non-compliance.
- 2. **Directives** Set out the required legislative aims to be achieved but leave the detail to the individual Member States. Directives only take effect when they are embodied in national legislation. Member States are given a transposition deadline, by which date national legislation must be introduce. This is usually between 18 months and 3 years. Differences in national interpretation can lead to uneven implementation of Directives.
- 3. **Decisions** These may be applicable to a Member State, an organisation or an individual within the Union. These are only binding upon the individual or institution to which they are addressed.

The ordinary legislative procedure - Consilium (europa.eu)

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## **CHCS Training**

CHCS offers Modular Training Courses on the writing of Safety Data Sheets (SDSs), and related issues such as classification, labelling and other documentation.

For more information see CHCS Training.

If you have any queries about our training, please Contact CHCS.

# **Chemicals Legislation Support From CHCS**

We provide a range of pages on the CHCS website that provide you with an introduction to many different aspects of chemicals legislation / regulation. These are grouped into the following headings:

- Brexit / GB & UK Legislation
- <u>European</u>
- Workplace
- Transport
- International

Click on the links above or visit the Legislation Introduction page.