

## Seminar series on Regulatory Toxicology II

- **03 October 2023 13.00 - 14.00**
  - **Peeter Pärt** (Swedish Agricultural University (SLU)) Introduction to the seminar series. Brief presentation of the EU governance system in general and decision making concerning chemical safety.
- **07 November 2023 13.00 – 14.00**
  - **Linda Spjuth** (European Chemicals Agency) .General presentation from ECHA with outlooks on how ECHA is using scientific information
- **05 December 2023 13.00 - 14.00**
  - **George Kass** (European Food Safety Authority) Presentation from EFSA and how EFSA is using scientific information in its work
- **23 January 2024 13.00 – 14.00**
  - **Elisabeth Berggren:** (European Commission – Joint Research Centre (JRC)) . Presentation of EU Reference Laboratory for alternatives to animal testing (EURL ECVAM)
- **12 March 2024 13.00 – 14.00**
  - **Magnus Lofstedt** (European Environment Agency (EEA)). Presentation from EEA work in the area of chemicals
- **09 April 2024 13.00-14.00**
  - **Dorota Jarosinska** World Health Organisation (WHO) Regional office for Europe). Presentation of the role of WHO concerning advise and actions on chemicals and chemical safety
- **14 May 2024 13.00 – 14.00**
  - **Jonathan Kleimark** (ChemSec – the International Chemical Secretariat).Presentation from an European Non Governmental Organization (NGO) in the area of chemical safety.

# Regulatory Toxicology II: European and International Perspectives

- This course is organized as a doctoral course with several mandatory components in addition to the seminar attendance *per se*. The mandatory elements of the course are:
  - Seminar attendance
  - Active preparatory and reflecting individual tasks for each seminar
  - One real life event at the end of the course
- The course is monitored by the Educational group of Swaccs
- A Course Certificate is issued by the Educational group. LADOK registration is the responsibility of home universities.
- The course can also be taken as a Continuing Education Course for postdocs and other professionals depending on the availability of course places.
- For application forms and the detailed course plan contact Helen Håkansson ([helen.hakansson@ki.se](mailto:helen.hakansson@ki.se)) or Anders Jidesjö ([anders.jidesjo@liu.se](mailto:anders.jidesjo@liu.se))

# Players and decision making in the European Union

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European Council

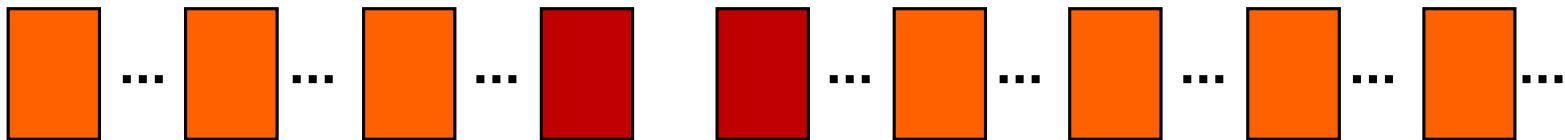
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The European  
Parliament

Council of  
European Union

The European Commission

“College” of 27 Commissioners



Directorates-General (DGs)

[https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/types-institutions-and-bodies\\_en](https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/types-institutions-and-bodies_en)

# European Commission

[https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-commission\\_en](https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-commission_en)

- **Proposes new laws**

- The Commission is the sole EU institution tabling laws for adoption by the Parliament and the Council that:
  - protect the interests of the EU and its citizens on issues that can't be dealt with effectively at national level
  - get technical details right by consulting experts and the public

- **Manages EU policies & allocates EU funding**

- sets EU spending priorities, together with the Council and Parliament
- draws up annual budgets for approval by the Parliament and Council
- supervises how the money is spent, under scrutiny by the Court of Auditors

- **Enforces EU law**

- together with the Court of Justice,
- ensures that EU law is properly applied in all the member countries

- **Represents the EU internationally**

- speaks on behalf of all EU countries in international bodies, in particular in areas of trade policy and humanitarian aid
- negotiates international agreements for the EU

# European Commission

## Composition:

- **Political leadership** is provided by a team of 27 Commissioners (one from each EU country) – led by the Commission President, who decides who is responsible for which policy area.
- The College of Commissioners is composed of the President of the Commission, eight Vice-Presidents, including three Executive Vice-Presidents, the High Representative of the Union for Foreign Affairs and Security Policy, and 18 Commissioners, each responsible for a portfolio.
- The **day-to-day running** of Commission business is performed by its staff (lawyers, economists, etc.), organised into departments known as Directorates-General (DGs), each responsible for a **specific policy area**.

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# European Commission

## Directorate Generals (DGs)

[https://commission.europa.eu/about-european-commission/departments-and-executive-agencies\\_en](https://commission.europa.eu/about-european-commission/departments-and-executive-agencies_en)

### DGs involved in chemicals policy and chemicals safety

- DG AGRI (Agriculture and Rural Development)
- DG CLIMA (Climate Action)
- DG COMP (Competition)
- DG EMPL (Employment, Social Affairs and Inclusion)
- **DG ENV (Environment)**
- **DG SANTÉ (Health and Food safety)**
- DG GROW (Internal Market, Industry, Entrepreneurships and SMEs)
- **DG JRC (Joint Research Centre)**
- **DG RTD (Research and Innovation)**
- DG Trade (Trade)

# European Parliament

[https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-parliament\\_en](https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-parliament_en)

## • Legislative

- Passing EU laws, together with the Council of the EU, based on European Commission proposals
- Deciding on international agreements
- Deciding on enlargements
- Reviewing the Commission's work programme and asking it to propose legislation

## • Supervisory

- Democratic scrutiny of all EU institutions
- Electing the Commission President and approving the Commission as a body. Possibility of voting a motion of censure, obliging the Commission to resign
- Granting discharge, i.e. approving the way EU budgets have been spent
- Examining citizens' **petitions** and setting up **inquiries**
- Discussing monetary policy with the European Central Bank
- Questioning Commission and Council
- Election observations

## • Budgetary

- Establishing the EU budget, together with the Council
- Approving the EU's long-term budget, the "Multiannual Financial Framework"



# The Council of the European Union

[https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/council-european-union\\_en](https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/council-european-union_en)

## What does the Council do?

- **negotiates and adopts EU laws**, together with the European Parliament, based on proposals from the European Commission
- **coordinates** EU countries' policies
- develops the EU's **foreign & security policy**, based on European Council guidelines
- concludes **agreements** between the EU and other countries or international organisations
- adopts the annual EU budget - jointly with the European Parliament

## Composition

- There are **no fixed members** of the EU Council. Instead, the Council meets in 10 different configurations, each corresponding to the policy area being discussed. Depending on the configuration, each country sends their minister responsible for that policy area.
- For example, when the Council meeting on economic and financial affairs (the "Ecofin Council") is held, it is attended by each country's finance minister.

# The European Council

[https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-council\\_en](https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-council_en)

## What does the European Council do?

- decides on the EU's overall **direction** and political **priorities** – but *does not pass laws*
- deals with **complex or sensitive issues that cannot be resolved** at lower levels of intergovernmental cooperation
- sets the EU's common foreign & security policy, taking into account EU strategic interests and defence implications
- nominates and appoints candidates to certain high profile EU level roles, such as the ECB and the Commission
- On each issue, the European Council can:
  - ask the European Commission to make a **proposal** to address it
  - pass it on to the Council of the EU to deal with

## Composition

- The European Council is made up of the heads of state or government of all EU countries, the European Council President, and the European Commission President.
- It is convened and chaired by its President, who is elected by the European Council itself for a once-renewable **two-and-a-half-year term**. Among other things, the President represents the EU to the **outside world**.

# EU decision-making process

[https://european-union.europa.eu/institutions-law-budget/law/how-eu-policy-decided\\_en](https://european-union.europa.eu/institutions-law-budget/law/how-eu-policy-decided_en)

- There are 3 main institutions involved in EU decision-making:
  1. the European Parliament, representing EU citizens
  2. the Council of the European Union, representing EU governments
  3. the European Commission, representing the EU's overall interests
- EU policies are typically decided through the ordinary legislative procedure (formerly known as the 'co-decision' procedure). This is a process where the three main institutions come to agreement on legislation.

# EU Environmental Policy

<https://www.europarl.europa.eu/factsheets/en/sheet/71/environment-policy-general-principles-and-basic-framework>

## Legal basis

- Articles 11 and 191 to 193 of the Treaty on the Functioning of the European Union (TFEU). The EU is competent to act in all areas of environment policy, such as air and water pollution, waste management and climate change. Its scope for action is limited by the **principle of subsidiarity** and the **requirement for unanimity** in the Council in the fields of fiscal matters, town and country planning, land use, quantitative water resource management, choice of energy sources and structure of energy supply.

# Health in EU

[https://health.ec.europa.eu/eu-health-policy/overview\\_en](https://health.ec.europa.eu/eu-health-policy/overview_en)

Primary responsibility for health protection and healthcare systems lies with the Member States. However, the EU plays an important role in improving public health, preventing and managing diseases, mitigating sources of danger to human health, and harmonising health strategies between Member States.

Public health policy has recently taken centre stage in EU policymaking with Parliament making cancer one of its areas of focus, the COVID-19 pandemic, and the Commission's work towards a stronger European Health Union.

## European Commission's role

DG SANTÉ supports the efforts of EU countries to protect and improve the health of their citizens and to ensure the accessibility, effectiveness and resilience of their health systems. This is done through various means, including by:

- proposing legislation
- providing financial support
- coordinating and facilitating the exchange of best practices between EU countries and health experts
- health promotion activities

# HEALTH IN EU

(CONTINUED)

## Legislation

The EU can adopt health legislation under the Treaty on the Functioning of the European Union: Article 168 (protection of public health), Article 114 (single market) and Article 153 (social policy). Areas where the EU has adopted legislation include

- Patients' rights in cross-border healthcare
- Pharmaceutical and medical devices (pharmacovigilance, falsified medicines, clinical trials)
- Health security and infectious diseases
- Digital health and care
- Tobacco
- Organs, blood, tissues and cells

## Council of the European Union recommendation

# Health in EU

(continued)

The Council of the EU can also address recommendations on public health to EU countries.

- Prevention of drinking of alcohol by young people (2001)
- Prevention of health-related harm associated with drug dependence (2003)
- Cancer screening (2003)
- Prevention of injury and the promotion of safety (2007)
- Patient safety, including the prevention and control of healthcare associated infections (2009)
- Action in the field of rare diseases (2009)
- Smoke-free environments (2009)
- Seasonal influenza vaccination (2009)



# EU agencies

[https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/institutions-and-bodies-profiles\\_en?f%5B0%5D=oe\\_organisation\\_eu\\_type%3Ahttp%3A//publications.europa.eu/resource/authority/corporate-body-classification/AGENCY\\_DEC](https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/institutions-and-bodies-profiles_en?f%5B0%5D=oe_organisation_eu_type%3Ahttp%3A//publications.europa.eu/resource/authority/corporate-body-classification/AGENCY_DEC)

## Regulatory Agencies

**ECHA** (European Chemicals Agency), Helsinki, Finland

**EFSA** (European Food Safety Authority) Parma, Italy

**EMA** (European Medicines Agency), Amsterdam, The Netherlands



# EU agencies

(continued)

## Advisory agencies (32 totally)

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**EEA** (European Environment Agency), Copenhagen, Denmark

**OSHA** (European Agency for Health and safety at Work), Bilbao, Spain

**ECDC** (European Centre for Disease Prevention and Control), Stockholm, Sweden

# Governmental organisations

## **UNEP** (United Nations Environment Program)

- The Stockholm Convention (Protecting human health and the environment from persistent organic pollutants) <https://www.pops.int/>

## **WHO** (World Health Organisation) [https://www.who.int/health-topics/chemical-safety - tab=tab\\_1](https://www.who.int/health-topics/chemical-safety-tab=tab_1)

## **IPCS** (International Program of Chemical Safety) WHO+ILO+UNEP

- Collaboration between three United Nations bodies, the World Health Organization, the International Labour Organization and the United Nations Environment Programme, to establish a scientific basis for safe use of chemicals

# Non Governmental Organisations (NGOs)

## **CEFIC** (European Chemical Industry Council)

- Founded represents large, medium and small chemical companies across Europe  
<https://cefic.org/about-us/>

## **HEAL** (Health and Environment Alliance) <https://www.env-health.org/>

## **ECETOC** (European Centre for Ecotoxicology and Toxicology of Chemicals)

- ECETOC works with leading scientists from academia, governments and industry to develop and promote trusted and practical scientific solutions which ensure a safe, sustainable and healthy world, <https://www.ecetoc.org/>

## **ChemSec** (International Chemicals Secretariat) <https://chemsec.org/about/>

## **PAN** (Pesticide Action Network - Europe) <https://www.pan-europe.info/>

- PAN is working for to minimise the negative effects of hazardous pesticides and to replace their use with ecologically sound and socially just alternatives.

## **IPCP** (International Panel on Chemical Pollution) <https://www.ipcp.ch/>

Extra: in case of time, interest and questions  
(not included in the original presentation)

## Principle of Subsidiarity

<https://eur-lex.europa.eu/EN/legal-content/glossary/principle-of-subsidiarity.html>

## Precautionary principle

<https://eur-lex.europa.eu/EN/legal-content/summary/the-precautionary-principle.html>

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