ISES Europe Training Series

DoE 7: Relevant Legislative Frameworks

Module 1: Introduction to the European Legislative Frameworks

Transcript Notice:

This is the transcript of the presentation. Please note that the actual spoken text may differ slightly from what is written here.

Slide 1 – Welcome
Hello and welcome to today's session in the ISES training series.
This presentation falls under Domain of Expertise 7: Relevant Legislative Frameworks. I'm delighted that you've joined us for this part of the training, and I look forward to guiding you through today's topic.

Slide 2 – Legal notice
Before we begin, just a quick legal note. All rights to the materials used here remain with the original copyright holders.
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Slide 3 – Overview of All Training Videos
This training is part of a broader ISES Europe initiative. In total, there are nine Domains of Expertise, together covering the breadth of exposure science.
They range from the fundamentals of exposure science and environmental chemistry, through topics like exposure modelling, risk communication, and sustainability, all the way to today's focus: legislation.
If you'd like to revisit any session, all training videos are available on the ISES Europe website (ises-europe.org).

Slide 4 – Domain of Expertise (DoE) 7
Our focus today is Domain of Expertise 7: Relevant Legislative Frameworks.
This domain is divided into three submodules:

- Module one, which we are covering today, introduces the principles of European legislative frameworks.
- Module two will focus on legislation under the remit of the European Food Safety Authority, or EFSA.
- Module three will address legislation under the remit of ECHA, the European Chemicals Agency.

Together, these modules provide a comprehensive picture of how legislation shapes the practice of exposure science in Europe.

Slide 5 – Module one
The title of today's session is *Introduction to the European Legislative Frameworks.*
We'll explore the role of key European institutions and the different types of legislation in the European Union. By the end, you should have a clearer picture of how legislation protecting the environment, workers and consumers is developed, and what the typical key processes are to enact it.

Slide 6 – Presenter
A few words about me before we begin. My name is Gerald Bachler. I currently work as a Regulatory Officer at the European Chemicals Agency, where I am a member of the Industrial Emission, Chesar and Exposure Group. Before joining ECHA, I worked on product safety in various companies within their Product Stewardship, Regulatory Affairs, and Toxicology/Risk Assessment teams.
I received a PhD in Nanotoxicology from ETH Zurich and hold an MSc in Health Care Engineering and in Health and Environmental Science.

Slide 7 – Context and Disclaimers
Please note that this lecture is designed as an introductory-level session. Some aspects have been simplified in order to provide a clear overview.
This presentation focuses on European legislation and reflects the situation at the time of recording. Some legislative details may have changed since then, so please keep that in mind as you watch.

Slide 8 – Content
Here is today's roadmap:

1. We'll start with a short introduction to the European Union.
2. Then, we'll move into three specific topics:
    - The key European Institutions
    - The types of legislation that exist in the EU
    - Some key European legislation that requires exposure science
3. Finally, we'll wrap up with a concise summary and the key takeaways.

Let's begin with the introduction.

Slide 9 – Introduction
The European Union is one of the largest economies in the world. It currently comprises 27 member states and is home to about 450 million inhabitants. As you can see from the map, including candidate countries, the European Union represents most of the European continent. We'll cover this in more detail later, but it's already clear that EU policies and legislation also significantly affect European countries that are not part of the EU.

The EU is also known for its high standards in environmental protection, occupational health, consumer safety, and food security. This is thanks to the legislation that the EU has put in place, requiring thorough risk assessments of substances, products and goods — a topic we'll explore further in this session.

Slide 10 – EU Legislation: A Complex Framework
The legal structure of the European Union is complex. This is partly due to the different legal traditions of its member states, and partly for historical reasons. The EU began as the European Coal and Steel Community with just six members and limited powers. Over time, it has evolved into a Union of 27 members, with competencies extending to consumer protection, environmental quality, human health, and worker protection.

The EU has 24 official languages, which are the national official languages of its 27 member states. Luxembourgish and Turkish, while official in Luxembourg and Cyprus respectively, are not EU official languages.

The EU pursues ambitious goals, such as the Chemicals Strategy for Sustainability, which often attempt to tackle a diverse set of challenges simultaneously.

Like many democracies, the EU legislative process involves multiple institutions. The most important ones we will discuss today.

Another factor adding complexity is that the European Council — composed of the heads of EU member states — largely works on a consensus basis.

Slide 11 – Learning objectives
By the end of this lecture, you should be able to:

- Understand the development of the legislative framework in Europe
- Explain the roles of key European institutions in the development and enforcement of legislation
- Distinguish between horizontal and vertical legislation
- Identify the key legislations that mandate an exposure assessment
- Know where to find more information

I encourage you to keep these objectives in mind as we move forward, so you can connect each section back to them.

Slide 12 – Content
Let's begin with an overview of the key European institutions.
This will give us a foundation for understanding the legislative process, and later, how each institution shapes the different types of legislation.

Slide 13 – The EU Institutions and Bodies
In principle, there are three categories of institutions and bodies in the EU:

- The seven European Institutions — of which four are the decision-making institutions. These are the European Council, the Council of the EU, the European Parliament, and the European Commission. We will discuss their roles on the next slides.
  The other three institutions, which we will not cover in detail today, are the Court of Justice, the European Central Bank, and the European Court of Auditors.
- Eight EU Bodies — These have more specialised roles, such as the European Ombudsman or the European Investment Bank. For completeness they are mentioned here, but at this high-level introduction we will not go into further detail.
- Around 30 European Decentralised Agencies — These agencies have their own legal personality and are established for an indefinite period. Some play a crucial role in implementing legislation to protect the environment, consumers, and workers. We will look at some of these later on.

Let's now take a closer look at the four EU decision-making institutions.

Slide 14 – European Decision-Making Institutions
First, let's look at the two legislative bodies of the EU, which hold the main power to adopt new legislation:

- The **European Parliament** consists of 720 Members of the European Parliament (MEPs), directly elected by EU citizens. Elections are held every five years, simultaneously across all 27 member states. The main seat of Parliament is Strasbourg, with additional offices in Brussels and Luxembourg.
- The **Council of the European Union** is the second legislative body. It is composed of 27 national ministers, one per member state. Its composition changes depending on the topic under discussion. Currently, the Council meets in 10 different configurations — for example, when discussing agriculture, the Council is formed by the 27 national agriculture ministers. Meetings are held in Brussels and Luxembourg.

Next to the legislative bodies, the EU has two executive bodies that ensure legislation is implemented, and that also hold the main role in proposing new laws:

- The **European Commission** is the EU's primary executive branch. It operates as a cabinet government and currently consists of 27 Commissioners, one from each member state, including the Commission President. Commissioners are nominated by national governments. The Commission is divided into departments known as Directorates-General (DGs), several of which play a key role in protecting workers, consumers, and the environment — such as DG Environment and DG Health and Food Safety (DG SANTE). The Commission is located mainly in Brussels and Luxembourg.
- The **European Council** should not be confused with the Council of the EU. It is composed of the heads of state or government of the member states, along with its own President and the President of the European Commission. It defines the EU's overall political direction and priorities, and normally works by consensus. It typically meets in Brussels.

Now that we know the four EU decision-making institutions, let's see how they work together.

Slide 15 – The Legislative Process of the EU
On this slide you see a simplified version of the EU's legislative process.

As mentioned, the European Council sets the EU's policy agenda. The European Commission is responsible for implementing this agenda and holds the primary role of proposing legislation. This is different from many member states, where national parliaments also have the right to propose laws.

The European Parliament does not have the right of initiative to propose legislation. Instead, together with the Council of the EU, its main role is to amend, approve, or reject proposals from the Commission. Parliament and the Council can request the Commission to submit a proposal, but the Commission decides whether to act.

For a proposal to become law, both Parliament and the Council must independently approve it.

- In Parliament, this requires a **majority** vote of MEPs.
- In the Council, most decisions require a **qualified majority** — at least 55% of countries (15 out of 27) representing at least 65% of the EU population. In some areas, such as taxation and foreign policy, unanimity is required.

Now that we know how EU legislation is created, let's turn to the decentralised agencies.

Slide 16 – Decentralised Agencies
Decentralised agencies are created to support the implementation of EU policies. They foster cooperation not only between EU institutions, but also with national authorities.

There are about 30 such agencies, distributed across member states, with most countries hosting at least one.

They are managed by independent boards and in principle operate separately from the EU institutions we discussed earlier. However, the European Commission approves their budgets and drafts the legislation that defines their scope of work, which must then be approved by both the European Parliament and the Council of the EU.

Slide 17 – European Decentralised Agencies
This slide lists the main European Decentralised Agencies involved in protecting the safety of workers, consumers, the general public, and the environment.

For more detail, we will focus specifically on the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) in Modules 2 and 3 of this Domain of Expertise, respectively.

Slide 18 – Involvement of Member States
Here I want to briefly highlight how the 27 EU member states are directly involved in the legislative and executive processes.

For the four decision-making institutions:

- In the **European Council**, member states are represented by their heads of state or government.

- In the **European Commission**, member states are not directly represented, but national governments nominate the 27 Commissioners.
- In the **European Parliament**, member states are represented through directly elected MEPs.
- In the **Council of the EU**, member states are represented by national ministers, depending on the policy area being discussed.

For the European Decentralised Agencies, each member state typically nominates one member to the Management Board and designates a competent authority to represent them in the agency's work.

And finally, enforcement of EU law is primarily carried out by the member states themselves.

Slide 19 – EU Legislation Beyond the EU
We are approaching the end of this section. As mentioned earlier, our focus here is on the EU. This is partly because the EU represents the majority of countries and population in Europe. But it is also because EU legislation strongly influences European countries outside the Union.

For example:

- Norway, Iceland, and Liechtenstein are connected through the European Economic Area (EEA). Many EU laws — such as the CLP and REACH Regulations — also apply in these countries.
- Switzerland participates in selected areas, such as ECHA's work on biocides.
- Candidate countries preparing to join the EU often align their national laws with EU legislation in advance. Other neighbouring countries with strong economic ties to the EU do the same, at least partly.

Consequently, with the likely exception of Russia and Belarus, EU legislation has some degree of impact in nearly every European country.

Slide 20 – Content
Let's now move on to our second major topic: *Types of Legislation in the European Union.*

Slide 21 – Types of Legislation in the EU
The three most important types of legislation in the European Union are shown on this slide. We will briefly discuss each of them separately:

1. **EU Regulations** — Today, these are the most common type of EU legislation. Once approved by the European Parliament and the Council of the EU, a Regulation is directly applicable in all member states.

2. **EU Directives** — Directives must be transposed into national law by each of the 27 member states. This allows for some differences in interpretation. While Directives set minimum standards that cannot be undercut, countries may adopt stricter rules in their national laws. As a result, alignment across member states is usually lower for Directives than for Regulations.
3. **National Laws** — For topics not regulated at the EU level, national governments can introduce their own laws. These may also complement EU legislation. For example, while nanomaterials must be registered under the EU's REACH Regulation, several member states considered EU requirements insufficient and enacted additional national legislation.

Slide 22 – Horizontal and Vertical Legislation
Let's move on to another way of categorising legislation:

- **Horizontal legislation** applies broadly across multiple sectors or policy areas. It sets common rules and principles that can be applied uniformly across different industries.
- **Vertical legislation** applies to a specific sector or policy area. It addresses the unique needs or goals of that particular field.

This distinction can sound abstract, so let's look at an example from the chemicals domain.

Slide 23 – Horizontal and Vertical Legislation for Chemicals
This slide illustrates the principle of horizontal and vertical legislation for chemicals.

For example, the CLP and REACH Regulations are considered **horizontal legislation**. They apply to virtually all chemicals and sectors, even though certain categories of chemicals are exempted from parts of them.

Let's take biocidal products and food additives as examples. These do not need to be registered under REACH, as sector-specific or **vertical legislation** defines separate registration processes with EFSA or ECHA. However, this exemption applies only to registration. These substances are not exempt from REACH's restriction provisions, meaning their use may still be limited under REACH in addition to the sector-specific rules.

This example shows how horizontal and vertical legislation interact.

Slide 24 – Content
With the main legislative principles covered, let's now look into some key pieces of European legislation that require exposure science.

Slide 25 – Legislations Using Exposure Information
In 2021, ISES Europe analysed how many EU chemical management laws make use of exposure information. The results are shown here.

For chemicals alone, there are 566 in-force regulations and directives containing references to "exposure." These cluster into 16 legislative domains, represented by the blue bubbles on the slide, that require exposure information.

From this, the importance of exposure science in the legislative context becomes very clear. Let's look at some concrete examples next.

Slide 26 – Key European Legislations
The list of legislations shown here is not exhaustive, nor will we discuss all of them in detail. Instead, they serve as examples of the wide variety of agents and sectors affected.

This slide also highlights that the case studies we'll cover in Modules 2 and 3 — which are some of the legislations under the remit of EFSA and ECHA — represent only a small part of the overall legislative landscape influenced by exposure science.

Slide 27 – When to Conduct an Assessment
As you may have noticed, the legislative landscape is complex — and so are the regulatory requirements for when and how exposure and risk assessments must be conducted.

In principle, assessments are required before a new product is placed on the market or when a production process is introduced or changed. But who must perform them, and what happens with the results, varies by regulatory domain.

- In some cases, **the producer or user is responsible**. For example, under REACH, Food Contact Materials, and Biocides. However, whether the assessment must be submitted or only kept on record also varies:
    - Under REACH, the assessment must be submitted to ECHA but is not reviewed before market placement.
    - For Food Contact Materials, the assessment must only be available on request.
    - For Biocides, assessments are submitted to ECHA and reviewed by regulators before authorisation.
- In other cases, the **authority itself carries out the assessment** before a product enters the market. Examples include some cosmetic ingredients, food additives, and authorised substances for plastic Food Contact Materials.

Slide 28 – Complexity of EU Legislation
Finally, let's look more closely at the complexity of EU legislation regarding exposure and risk assessment.

- Overlap of regulations is common — for example, REACH overlaps with Occupational Safety and Health Directives.
- Multiple legislations may apply to the same product group. For instance, environmental risks of cosmetics are addressed via REACH, while consumer risks are addressed through the Cosmetics Regulation.
- Different requirements exist within a single sector — Food Contact Materials are a prime example, where rules vary widely depending on the material.

We will illustrate these complexities on the next two slides, using Food Contact Materials and Biocides as an example.

Slide 29 – FCM: Complexity Example
At the time of recording, Food Contact Materials (FCMs) are regulated differently depending on the material:

- Some, like plastics and ceramics, are regulated at the EU level.
    - Ceramics are regulated through an EU Directive.
    - Plastics are regulated through several EU Regulations.
    - For plastics, there is a positive list of authorised substances, but producers must also perform migration testing. Even when authorised substances are used, testing for impurities is still required.
- Other FCMs, such as paper, cardboard, and silicone, are regulated only at national level, where requirements differ widely. Some countries lack specific rules altogether or rely only on recommendations.
  Because products approved in one member state can generally circulate freely across the EU under the free movement of goods principle, producers may choose to comply with the standards of the member state they find most favourable.

This is still a simplification, but it illustrates the complexity of exposure and risk assessments in Europe. Now, let's move to our second example.

Slide 30 – Biocides: Complexity Example
Biocides also present several layers of complexity. Again, this is a simplified overview:

- **Registration overlap**: Active substances under the Biocidal Products Regulation (BPR) are considered registered under REACH, so no separate REACH registration is needed. However, biocides used in cosmetics and plant protection products are excluded from the BPR, so they must still be registered under REACH. Additionally, for cosmetics, REACH registration covers only environmental risks; human health of end users is assessed under the Cosmetics Regulation. This means that a biocidal active substance may require an exposure and risk assessment in compliance with the Biocidal Product Regulation, REACH Regulation and the Cosmetic Regulation.
  Note, co-formulants, i.e. non-active substances in biocidal products, must also be registered under REACH.
- **Mutual recognition**: Normally, once a biocidal product is authorised in one member state, it can be recognised in others. However, for some pest control products, this does not apply, and separate authorisations are required in each country.
- **Transition phase**: A transitional arrangement allows national rules to continue applying to biocidal active substances not yet fully evaluated under the EU system. Originally expected to last only a few years, this transition has now stretched close to 25 years. The new deadline for completing the EU-wide evaluation of all biocidal active substances currently on the market is 2030 — still an ambitious goal given the progress so far.

Slide 31 – Content
Now that we've covered all three sections of this presentation, let's bring everything together with a short summary.

Slide 32 – Summary: Key Takeaways
European legislation is complex but structured. Many institutions and frameworks shape the legislative process. Contrary to popular belief, decisions are largely driven by the member states, and each state is represented in multiple ways throughout the process.

There are four main institutions driving European legislation: the European Commission, the European Parliament, the European Council, and the Council of the EU.

Two main types of legislation exist: horizontal and vertical. Horizontal legislation applies across sectors, while vertical legislation targets specific industries or fields.

And last but not least, many laws require an exposure and risk assessment. These assessments help ensure the protection of the environment, workers, consumers, and the general public.

Slide 33 – Where to Find More Information?
Here you'll find a list of additional resources to explore. These are primarily the official websites of EU institutions and their decentralised agencies.

If you are working in this field — or expect to in the future — I strongly encourage you to consult these documents directly. They provide insights that go well beyond what we could cover in today's overview.

Slide 34 – Consequent Modules

Looking ahead, **Module two and three** of this training will turn to legislation under the remit of **EFSA – the European Food Safety Authority**, and **ECHA—the European Chemicals Agency**. And further down the line, ISES Europe may release additional specialised materials, allowing us to explore individual topics in greater depth.

Slide 35 – Closing thanks

That brings us to the end of today's session.
Thank you very much for your attention and participation. I hope the material has given you a clear understanding of how EFSA operates within the legislative landscape, and how exposure and risk assessments are integrated into food safety regulation.
Please continue exploring ISES Europe's training series for more insights into exposure science and risk assessment.
As a reminder, all training materials are available on the ISES Europe website (**ises-europe.org**).

Slide 36 – Further Reading

On this final slide, you'll find suggested reading materials for further study relating to chemical regulation in Europe. We won't go through them here, but I highly recommend you review them afterwards.
Thank you very much, and goodbye.
