ISES Europe Training Series

DoE 7: Relevant Legislative Frameworks

Module 3: Legislation under the Remit of ECHA

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 very glad 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 are retained by their 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, which together cover the full breadth of exposure science.
They range from fundamental principles 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 introduced the principles of European legislative frameworks.
- Module two focused on legislation under the remit of the European Food Safety Authority, or EFSA.
- Module three, which we are exploring today, deals with 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 three

The title of today's session is *Legislation under the Remit of ECHA*.
We'll explore how exposure and risk assessments are applied in ECHA's context, and how they influence decisions that directly affect the safety of the environment, workers, and consumers. By the end, you should have a clearer picture of the processes, responsibilities, and outcomes tied to ECHA-related legislation.

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 part of the Industrial Emissions, Chesar, and Exposure Group. Before joining ECHA, I worked in product safety for various companies in Product Stewardship, Regulatory Affairs, and Toxicology/Risk Assessment teams.
I hold a PhD in Nanotoxicology from ETH Zurich, as well as an MSc in Health Care Engineering and Health & Environmental Science.

Slide 7 – Context and Disclaimers

Please note that this lecture is designed as an introductory-level session. Some aspects have been simplified to provide a clear overview.
This presentation focuses on European legislation and reflects the situation at the time of recording. Keep in mind that some legislative details may have changed since.

Slide 8 – Content

Here is today's roadmap:

1. We'll start with a short introduction to ECHA and its remit.
2. Then, we'll move into three specific regulatory fields where exposure and risk assessment play a critical role:
    - REACH Regulation
    - Biocidal Products Regulation (BPR)
    - Cosmetics Regulation
3. Finally, we'll wrap up with a concise summary and the key takeaways you should leave with.

Let's begin with the introduction.

Slide 9 – Introduction

The European Chemicals Agency (ECHA) is a decentralised EU agency located in Helsinki, Finland. For more details about decentralised EU agencies in general, I encourage you to revisit Module 1.

ECHA's remit essentially covers the management and implementation of EU chemicals legislation to ensure the safe use of chemicals. On the slide, you can see — on the left — the legislation where ECHA has responsibilities, and on the right, the Committees hosted by ECHA.

Please note that at the time of recording, the Scientific Committee on Consumer Safety is *not yet* managed by ECHA. However, the European Commission has several times expressed the intention to move this Committee under ECHA's remit. This is also reflected in the draft "Basic ECHA Regulation," which would formalise all of ECHA's roles. At present, ECHA's legal definition stems mainly from the REACH Regulation, but its workload today extends far beyond REACH, as can be seen on the slide.

For this lecture, we will zoom in on three areas where exposure science plays a particularly visible role:

- Industrial chemicals regulated under the REACH Regulation and some of the roles that the Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) play there.
- Biocidal active substances and products regulated under the BPR and some of the roles that the Biocidal Products Committee (BPC) plays there.

- At the end, cosmetic ingredients regulated under the Cosmetics Regulation and some of the roles that the Scientific Committee on Consumer Safety (SCCS) plays there.

Slide 10 – Learning objectives

By the end of this lecture, you should:

- Have a clear understanding of the legal requirements for exposure assessments in relation to industrial chemicals, biocides, and cosmetics.
- Know where to find additional, more detailed information if you need to explore a specific topic further.

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

Slide 11 – Content

Let's begin with industrial chemicals.
This will allow us to see how exposure and risk assessments are carried out for such substances.

Slide 12 – Exposure Assessment: REACH

Let's look at the main REACH processes that require an exposure and risk assessment. Simply put, this happens in three cases:

- When an industrial substance is registered under REACH, is hazardous and is produced or imported at 10 tonnes or more per year by a company located in the European Economic Area.
- When a substance is restricted due to identified risks and listed in Annex XVII of the REACH Regulation.
- When a company requests authorisation to use a substance included in Annex XIV of the REACH Regulation.

These exposure and risk assessments are typically substance-based and focus on individual chemicals. However, ECHA is increasingly working to also consider cumulative exposure.

Slide 13 – Exposure Assessment: Registration

First, let's look at exposure and risk assessments required for the registration of chemicals under REACH. Such an assessment is needed when two conditions are met:

1. The substance is produced and/or imported in quantities over 10 tonnes per year by a registrant/company (per legal entity).
2. The substance is classified as hazardous for at least one endpoint.

When an exposure and risk assessment is required, it forms part of the so-called Chemical Safety Assessment (CSA). This assessment must be carried out by the registrant and attached to the submission files submitted to ECHA. Importantly, this must happen *before* the substance is placed on the market.

The registrant must also keep the CSA continuously up to date. For example:

- If new uses are identified, they must be added before marketing.
- If new toxicological data becomes available, it must be considered and reflected in the CSA where relevant.

The CSA must include exposure and risk assessments for all identified uses. The conclusions for each use are communicated in the Annex of the Safety Data Sheet (SDS), in so called Exposure Scenarios (ES).

Each Exposure Scenario must describe the Conditions of Use — for example, use amounts or risk management measures such as room ventilation — that enable workers and consumers to use substances safely. For consumer products, however, risk management measures should not be assumed at the point of use. Instead, the registrant must communicate safe limits (e.g., maximum concentrations or use amounts) to formulators of final consumer products.

Slide 14 – Exposure Assessment: Registration

Submitted CSAs are only reviewed by ECHA for compliance with formal requirements. A detailed technical check of the exposure and risk assessment content is *not* part of the submission process.

So, how are CSAs scrutinised?
Under REACH, the responsibility for reviewing registrations lies with EU Member States. Together with ECHA, they have developed a prioritisation scheme. Substances with higher priority are selected — usually by one Member State — for in-depth evaluation.

Based on this evaluation, a Member State can propose further regulatory action to manage risks, such as:

- Harmonised classification and labelling

- A binding or indicative Occupational Exposure Limit (OEL) at EU level
- Restricting the substance's use
- Inclusion in the Candidate List of Substances of Very High Concern (SVHC), which can later lead to its addition to the Authorisation List (Annex XIV)

In addition, while ECHA does not check the CSA content upon submission, the information is accessible to labour inspectors across the EEA. Inspectors can check whether Conditions of Use and risk management measures are correctly communicated in the SDS and whether they are being implemented by downstream users. Note, the Conditions of Use and risk management measures described in the SDS are legally binding obligations.

Slide 15 – Exposure Assessment: Restriction

An exposure and risk assessment is also required when a substance is restricted under REACH. Restrictions can be proposed by a Member State or by ECHA, but ECHA can only do that at the request of the European Commission.

The party initiating the restriction is responsible for drafting a restriction dossier. This dossier must:

- Clearly define the uses to be restricted
- Provide an exposure and risk assessment demonstrating that these uses present unacceptable risks requiring regulation

Unlike registration or authorisation (which focus on individual substances), restrictions can also cover:

- Groups of substances with similar properties, e.g., the ongoing PFAS restriction
- Groups of substances by hazard class, e.g., CMRs in consumer products
- Substances not registered under REACH, e.g., the Microplastics restriction

A restriction does not necessarily mean a complete ban. It may instead set a maximum concentration in certain uses, require specific risk management measures, or require compliance with derived no-effect levels (DNELs). Uses not addressed in the restriction remain allowed.

Restriction dossiers are scrutinised by both the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC). Their joint opinion is then sent to the European Commission, which formally adopts the restriction by adding it to Annex XVII.
Note, while the Commission is not legally bound to joint RAC/SEAC opinions, in practice it almost always follows them fully.

Slide 16 – Exposure Assessment: Authorisation

An exposure and risk assessment is also required under the authorisation process. To simplify:

1. First, a substance must be identified as an SVHC and added to the Candidate List.
2. In a second step, it can be included in Annex XIV of REACH, also called the Authorisation List.

Once a substance is on Annex XIV, all uses are prohibited by default unless a company requests authorisation for a specific use. To do so, the company must prepare an authorisation dossier with an exposure and risk assessment demonstrating that the substance can be handled safely.

This dossier is reviewed by RAC and SEAC. If granted, authorisation is always time-limited, and companies must reapply before it expires. Each Annex XIV entry also includes a "sunset date" after which no new authorisation applications are accepted.

Slide 17 – Content

Let's move on to our second major topic: the Biocidal Products Regulation, often abbreviated as BPR.

Slide 18 – Exposure Assessment: Biocides

Now let's look at the approval process for biocidal active substances, and in a second step, the authorisation process for biocidal products.
A biocidal product consists of the active substance together with co-formulants, as it is marketed.

The two processes differ significantly but share some similarities with the approval of plant protection products, which we covered in Module 2.

Slide 19 – Exposure Assessment: Active Substance

Approval of the active substance is required before any biocidal product can be authorised.

- There is no tonnage threshold: approval is required regardless of market volume.
- Approvals are typically valid for 10 years, though shorter periods are possible.
- Applicants must submit a comprehensive dossier for each *Product Type* (PT). There are 22 PTs defined in the Regulation.

Each dossier usually includes:

- Physico-chemical properties
- Toxicological and ecotoxicological data
- Efficacy data
- Environmental fate and behaviour data
- An exposure and risk assessment, focused on representative uses within the PT

The exposure section often differs significantly across PT dossiers, even for the same active substance. Assessments cover all activities associated with the representative use, including aggregate assessments and secondary exposure.

The Biocidal Products Committee (BPC) then evaluates the dossier. One rapporteur Member State is appointed to lead the evaluation, using the dossier from the registrant to prepare the Competent Authority Report (CAR), which forms the basis of the approval decision.

Slide 20 – Exposure Assessment: Biocidal Product

The authorisation of a biocidal product follows the same overall principles as active substance approval, but with important differences.

- The exposure and risk assessment must be done for each identified use, reflecting real market conditions. This often means several uses are assessed within one product authorisation report.
- The entire product is assessed — not only the active substance but also co-formulants and potential interactions between ingredients.

Applicants can request EU-wide authorisation. In that case, the dossier is reviewed by the Biocidal Products Committee, with one rapporteur Member State leading the evaluation. If granted, the authorisation is valid across the EU.

Alternatively, applicants can request authorisation in a single Member State. In this case, that state alone evaluates the dossier and decides. This authorisation can later be extended to other Member States via the mutual recognition procedure, but the applicant must initiate this.

Slide 21 – Content

With biocides covered, we now turn to our third and final major topic: cosmetics.

Slide 22 – Exposure Assessment: Cosmetic Products

Our final example concerns cosmetic products. As mentioned earlier, any environmental risk assessment requirements for cosmetic ingredients are addressed under REACH. Here, we will focus on human health risks for consumers.

For cosmetics, the responsibility for carrying out an exposure and risk assessment lies with the product manufacturers. The Scientific Committee on Consumer Safety (SCCS), on the other hand, provides expert assessments in specific cases.

The Cosmetics Regulation specifies both the role and requirements for producers, as well as the role of the SCCS. We'll first discuss company responsibilities, then the SCCS.

Slide 23 – Exposure Assessment: Companies

Before placing a cosmetic product on the market, producers must carry out an exposure and risk assessment. This assessment must:

- Focus on the product as a whole and consider all ingredients.
- Take secondary exposure into account, e.g., exposure to non-users who may come into contact with the product via another person.
- Check compliance with the positive and negative lists in the Cosmetics Regulation.
    - Positive lists exist for colourants, preservatives, and UV filters. Ingredients not listed here are, by default, not permitted.
    - Negative lists specify substances that are prohibited, or only allowed under strict conditions.
- Be kept on file by the producer. Note: it does not need to be submitted proactively to authorities, but must be made available if requested by a competent authority.

Now, let's move to the role of the SCCS.

Slide 24 – Exposure Assessment: SCCS

The role of the SCCS is limited to performing expert exposure and risk assessments in specific situations, including:

- Substances classified as CMR (Carcinogenic, Mutagenic, or Reprotoxic)
- Nanomaterials
- Other substances when requested by the European Commission or a Member State

Third parties such as producers, health professionals, or academics cannot directly request an SCCS assessment. They must first raise concerns with the Commission or a Member State, which can then mandate the SCCS to act.

Additionally, the SCCS provides guidance to producers on how to conduct risk assessments. These guidelines define, for example:

- Physiological assumptions such as body weight and skin surface area
- Typical use amounts for different cosmetic product categories

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Slide 25 – Content

Now that we've covered all three main regulatory areas, let's bring everything together in a short summary.

Slide 26 – Summary: Key Takeaways

The processes for exposure and risk assessment differ significantly depending on the legislation:

- In some cases, the authority performs the assessment itself — for example, the SCCS's work with cosmetics, or the preparation of a REACH restriction dossier.
- In others, producers are fully responsible, such as with REACH registrations.
- In yet other cases, responsibility is shared, as in the authorisation of biocidal products.

Safe thresholds are central in all three systems, but they are derived and applied in very different ways.

Communication of safe use also varies:

- For REACH, it happens via Exposure Scenarios in the Safety Data Sheet to all users along the supply chain.
- For Cosmetics, restrictions often specify exact conditions of safe use that have to be considered by cosmetic formulators.

The scope of assessment differs: sometimes individual substances, sometimes groups of substances, sometimes entire products, sometimes cumulative exposure.

Physiological and use assumptions (e.g., exposure factors, body weight, usage patterns) also vary by framework.

Slide 27 – Where to Find More Information?

Here you'll find a list of additional resources to explore.
If you are working in this field or expect to in the future, I strongly encourage you to consult these documents directly. They provide detailed methodologies, case studies, and regulatory requirements that go far beyond what we can cover in today's overview.

Slide 28 – Consequent Modules

This was our final module in this Domain of Expertise.
In the future, ISES Europe may release additional specialised materials, allowing us to explore individual topics in greater depth.

Slide 29 – 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 ECHA operates within the legislative landscape, and how exposure and risk assessments are integrated into chemical 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 ISES Europe website (**ises-europe.org**).

Slide 30 – 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 to review them afterwards. They will give you deeper insights into the methodologies, case studies, and regulatory details that complement today's overview.

Thank you very much for your attention — and goodbye.
