DoE 7: Relevant Legislative Frameworks

ISES Europe Training Series

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Overview of All Training Videos

DoE 1) Basic Concepts and Principles in Exposure Science

DoE 2) Fundamentals of Environmental Chemistry and (Eco)Toxicology

DoE 3) Exposure Modelling

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DoE 5) Exposure Assessment and Risk Characterisation

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Domain of Expertise (DoE) 7:
Relevant Legislative Frameworks

Module 1 Introduction to the European Legislative Frameworks

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DoE 7: Relevant Legislative Frameworks

Module 3

Legislations Under the Remit of ECHA

Gerald Bachler

Presenter

Meet Today's Presenter: Gerald Bachler

- **Current Role: Regulatory Officer | European Chemicals Agency** (2024 – Present)
- **Previous Roles:**
  - **DuPont (2019–2024):** Manager, Product Stewardship & Regulatory Affairs; Led global regulatory submissions, risk assessments, and safety initiatives.
  - **Vitis Regulatory (2017–2019):** Principal Exposure Scientist; Specialising in exposure and risk assessment for industrial chemicals.
  - **Shell (2015–2017):** Exposure Scientist/Industrial Hygienist; Handling risk assessments and ensuring REACH and CLP regulatory compliance.
- **Education:**
  - **PhD in Nanotoxicology,** ETH Zürich; **MSc in Health Care Engineering**, Technical University of Graz; **MSc in Health and the Environment**, Cranfield University.
- **Certification:** Swiss Certified Safety Engineer.

Context and Disclaimers

About This Lecture

This lecture provides an **introductory framework**, with some topics simplified for ease of understanding. It focuses solely on the **situation in Europe**.

Disclaimer

- The regulatory landscape in Europe is constantly evolving. This presentation was prepared in 2024, and some aspects may no longer be applicable by the time you view the video.
- The content in **this presentation** is intended for general informational purposes only and **does not, nor is it meant to, constitute legal advice**.
- Many legal considerations are subject to interpretation, and conclusive answers may only be provided through a court ruling.
- The content presented herein does not necessarily reflect the opinions, views, or positions of the presenters' employer or any affiliated organizations.
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Introduction

ECHA (European Chemical Agency) is a decentralised EU agency

ECHA has enforcement responsibilities in the following EU legal acts:

- **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation**
- **Biocidal Product Regulation (BPR)**
- Prior Informed Consent Regulation (PIC Regulation)
- Classification, Labelling and Packaging (CLP) Regulation
- Drinking Water Directive (DWD)
- Batteries Regulation
- Waste Framework Directive (WFD)
- Persistent Organic Pollutants (POPs) Regulation

Committees hosted by ECHA:

- **Committee for Risk Assessment (RAC)**
- **Committee for Socio-Economic Analysis (SEAC)**
- **Biocidal Products Committee (BPC)**
- ***Scientific Committee on Consumer Safety (SCCS)****

**Move to ECHA considered under the One Substance, One Assessment (OSOA) initiative*

Learning Objectives

- Understand the fundamental legal requirements for exposure assessments under the following regulations:
  - REACH Regulation
  - Biocidal Product Regulation (BPR)
  - Cosmetics Regulation
- Remember where to find more information

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Exposure Assessment: REACH

Processes requiring exposure and risk assessments:

- **Substance Registration:** Demonstrating safe use for substances manufactured/imported at 10 tonne or more per year
- **Restriction (Annex XVII):** Limits or bans on substances due to identified risks
- **Authorisation (Annex XIV):** Applications to use SVHCs by proving control and/or socio-economic benefits

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Typically substance-based, assessing risks and exposure for individual chemicals

Exposure Assessment: Registration

Required for substances meeting the following criteria:

- Produced or imported in quantities over 10 tons per year
- Classified as hazardous for at least one endpoint

Exposure assessment as part of the Chemical Safety Assessment (CSA):

- Conducted by the registrant or company
- Must be submitted to ECHA before the substance is placed on the market
- Must be kept up to date with any changes

Exposure Scenarios (ES) for each identified use:

- Registrants are required to include safe use instructions for each ES in the Safety Data Sheet (SDS) provided to downstream users

Exposure Assessment: Registration

Submitted CSA may be reviewed by Member States, potentially leading to further regulatory actions, such as:

- Harmonised classification
- Harmonised Occupational Exposure Limits (OELs)
- Restrictions
- Inclusion on the SVHC list and subsequent authorisation requirements

Implementation checks:

- Labour inspectors may verify if the Risk Management Measures (RMMs) outlined in the SDS are correctly implemented by downstream users

Exposure Assessment: Restriction

A restriction procedure can be initiated by a Member State (MS) or ECHA at the request of the European Commission

MS or ECHA are responsible for drafting the restriction dossier, which includes:

- Focus on specific uses, the entire substance, groups of substances, or certain classifications.
- Exposure and risk assessments.
- Possible outcomes, such as:
  - Maximum concentration limits for certain uses.
  - Requirements for specific risk management measures (RMMs).
  - Mandatory derived no-effect levels (DNELs).
- Uses not addressed in the restriction dossier remain unrestricted.

The dossier is reviewed by the RAC and SEAC before enforcement.

Exposure Assessment: Authorisation

- The authorisation process requires a substance to:
  - First, be included in the Candidate List (SVHC list)
  - Then, be added to Annex XIV of REACH (the "Authorisation List")

  → This generally prohibits all uses unless specifically authorised
- **Authorisation applications must be submitted by users of the substance**:
  - The application dossier includes a detailed exposure and risk assessment
- **Applications are reviewed by the RAC and the SEAC before authorisation is granted**
- Regular re-application for authorisation is required to maintain use

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Exposure Assessment: Biocides

Two step process:

- Approval of an **Active Substance**
- Authorisation of a **Biocidal Product**

Both the active substance (material) and the final biocidal product require thorough evaluation, with distinct processes for each

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Exposure Assessment: Active Substance

- Approval required before biocidal product authorisation:
  - No tonnage limit
  - Renewal at least every 10 years
  - One safe use must be shown
- Exposure assessment (part of risk report) by registrants/companies:
  - Typically, one report per product type (PT)
  - Includes all activities and secondary exposure
- Biocidal Products Committee (BPC) reviews application:
  - One member state typically leads review of the submission
  - Risk report submitted by applicant is adapted to form Competent Authority Report (CAR)

Exposure Assessment: Biocidal Product

- Authorisation required before market placement:
  - No tonnage limit
  - Renewal at least every 10 years
- Exposure assessment (part of the Product Assessment Report) by registrants/companies:
  - Includes all activities for each identified use, including secondary/indirect exposure
  - Focus on the entire product/mixture
- Authorisation granted by:
  - Biocidal Products Committee (BPC), with one MS in the lead, valid EU-wide
  - Member State, extendable to other countries by the registrant

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Exposure Assessment: Cosmetic Products

The Cosmetics Regulation **focuses solely on human health**, while environmental exposure and risk assessments are covered under the REACH Regulation.

Companies placing cosmetic products on the market **are required to conduct exposure and risk assessments**. Additionally, **the Scientific Committee on Consumer Safety (SCCS) provides expert assessments**.

→ The Cosmetics Regulation specifies the exact requirements for these assessments

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Exposure Assessment: Companies

Companies shall conduct a safety assessment, including an exposure assessment, meeting the following:

- The assessment must focus on the product as a whole and consider all ingredients
- Secondary exposure must also be taken into account
- The assessment must comply with the positive and negative lists outlined in the Cosmetics Regulation
- The safety assessment must be retained and made available upon request by the relevant Member State authority

Exposure Assessment: SCCS

The Scientific Committee on Consumer Safety (SCCS) shall carry out exposure and risk assessment for:

- CMR substances (aggregated assessment)
- Nanomaterials
- Other substances that where concerns have been flagged, by a member state or commission, which could have been raised by various third parties, e.g., producer, health professionals, academics, etc.

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Summary: Key Takeaways

- An assessment may follow **different processes** depending on the context:
  - Producer vs. regulator/authority
  - Safe threshold benchmark values
  - Communication of safe use
- Exposure assessment **requirements vary across legislation**:
  - Substance vs. product focus
  - Consideration of aggregated and cumulative exposure
  - Physiological and use assumptions of humans

Where to Find More Information?

- **REACH: Guidance on Information Requirements and Chemical Safety Assessment**
  - https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
- **Guidance on Biocides Legislation**
  - https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation
- **SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation**
  - https://single-market-economy.ec.europa.eu/sectors/cosmetics/scientific-and-technical-assessment_en
- **SCCS - Opinions**
  - https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs/sccs-opinions_en

Consequent Modules

Future training videos:

- Additional legislations may be covered by ISES Europe in specialised training videos.

Thank You!

We appreciate your participation and attention

We encourage you to explore other ISES Europe training videos for deeper insights and broader understanding

Access all videos via: **https://ises-europe.org/**

Further Reading

Overview of European Chemicals Legislation

Chemical Safety in Science Education, CheSSE

https://chesse.org/legislation/overview-of-european-chemicals-legislation/

Mapping of Data Requirements and Assessment Methodologies Linked to the Regulatory Frameworks and Remits of the Relevant EU Agencies (ECHA, EFSA and EMA) and EC Scientific Committees (SCCS and SCHEER) – Final Report

RPA Europe and Forschungs- und Beratungsinstitut Gefahrstoffe GmbH (FoBiG)

https://www.efsa.europa.eu/en/supporting/pub/en-8540

Occupational Safety and Health

German Federal Ministry of Labour and Social Affairs

https://www.bmas.de/EN/Labour/Occupational-Safety-and-Health/occupational-safety-and-health.html

Industrial Emissions Directive

European Commission – Directorate-General for Environment

https://environment.ec.europa.eu/topics/industrial-emissions-and-safety/industrial-emissions-directive_en