PAKISTAN TEXTILE COUNCIL

Comprehensive guide:

REACH REGULATION

July 2025

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Acknowledgements

This guide was prepared as a supplementary resource to support industry stakeholders and policymakers in navigating the requirements of the REACH Regulation (Regulation (EC) No 1907/2006). It is intended to serve as an accessible reference and training tool, particularly for those engaging with or affected by EU chemicals legislation. While every effort has been made to ensure accuracy, this guide does not replace the official legal text and should be used in conjunction with the full REACH regulation and ECHA guidance.

July 2025
Pakistan Textile Council

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1. INTRODUCTION

1.1 BACKGROUND

Chemical substances are applied in various industries for many uses. Specifically in the textile industry, these can be found in dyes, used to improve the functionality of cloth and are present to give fabrics different finishes.[1] While the benefits do exist, these substances pose a significant threat to human health and the environment. Around 68 million tonnes of hazardous substances to the environment were produced in 2023.[2.] It is estimated that lead exposure increases the chances of cardiovascular disease deaths by sixfold and, in 2019, its global cost of exposure was USD 6 Trillion.[3] Currently, to mitigate these impacts, there are approximately 40 laws in the European Union (EU) that regulate use of chemicals.[4]

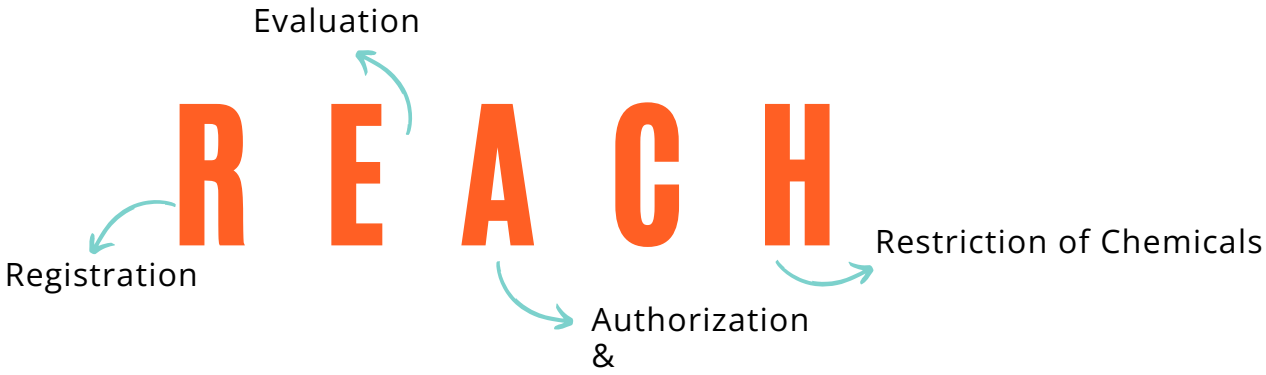
Example:

Chemicals in Textiles

1. Formaldehyde to prevent creases
2. Azo dyes for bright colours
3. Cadmium, lead, mercury, chromium VI used in dying
4. Phthalate esters to enhance the flexibility and durability

All these chemicals have documented harmful impact on human health and environment

Source: Allergy Standards and Environmental Toxicology and Pharmacology Journal



1.2 Overview of REACH Regulation

REACH (EC Regulation No 1907/2006) was developed to ensure that substances of very high concern (SVHC) are handled responsibly, to mitigate their impact on human health and the environment, as well as to encourage research to develop alternative production processes and alternative, less harmful, substances. Its core principles are:

1. Responsibility lies with industry
Those who manufacture, import, market, or use substances must ensure safety and manage associated risks.

2. Information-driven
Data on substances must be collected and passed down the supply chain.

Substances that do not comply with the registration conditionalities will not be placed in the market or manufactured in the community. The REACH regulation also places focus on reducing verbatim animal testing and developing and utilizing less hazardous substances.

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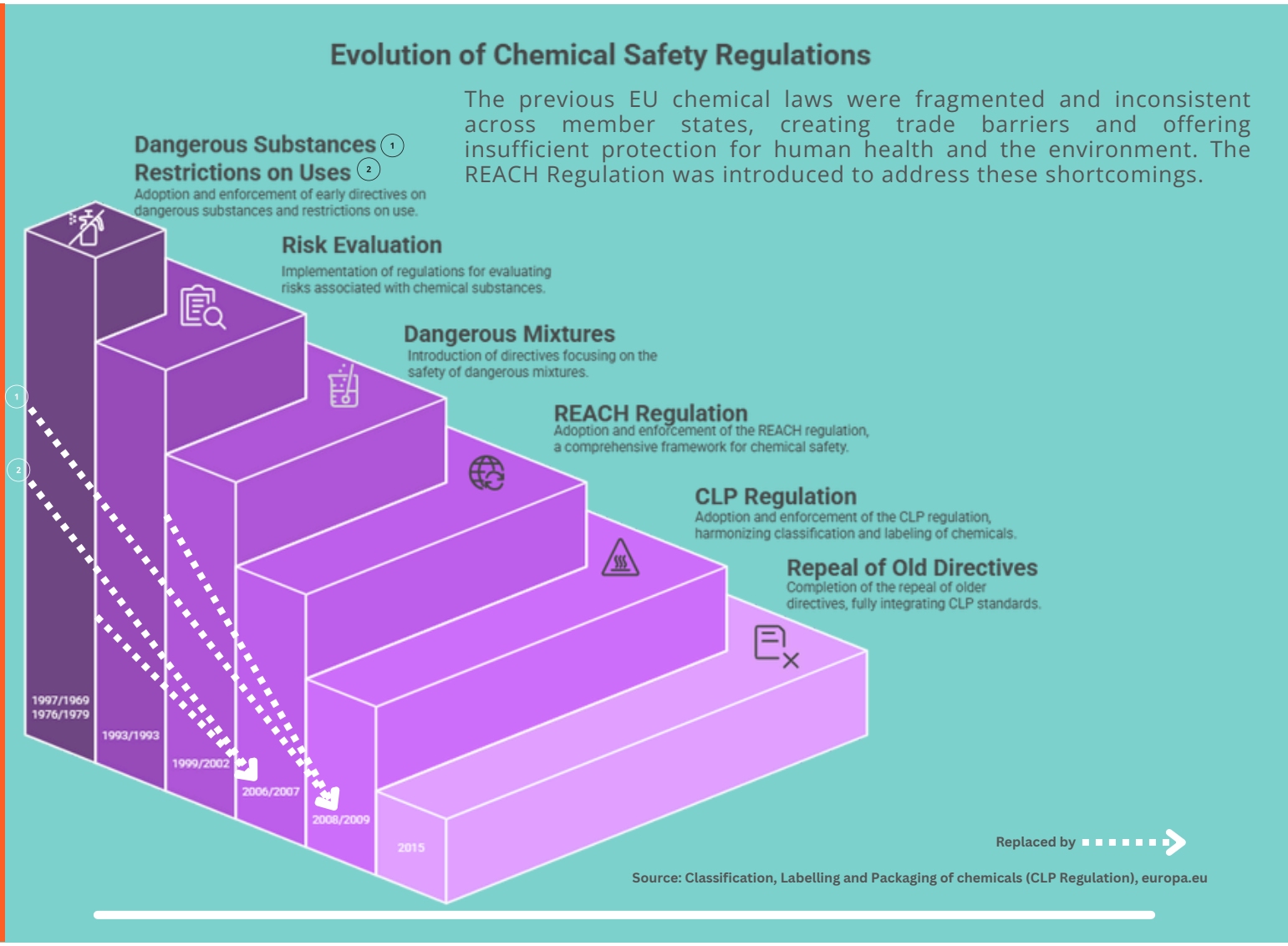
1. QIMA, "REACH Compliance for Textile Production."
2. Eurostat, "Production and Consumption of Chemicals."
3. Larsen and Sánchez-Triana, "Global Health Burden of Lead Exposure."
4. European Commission, "EU Chemicals Strategy."

2. SCOPE AND APPLICABILITY

2.1 EU CHEMICAL SAFETY LEGISLATIVE LANDSCAPE



2.2 European Chemical Agency (ECHA)

While REACH regulation was being drafted, a feasibility study was carried out that recommended a centralized body to minimize costs and ensure transparency, ultimately leading to ECHA's creation in June 2007.[5] This central body acts as the technical and scientific secretariat of REACH and coordinates work with EU member states, the European Commission (EC), and industry stakeholders. According to ECHA, from the time frame of 2009-2024, ECHA has successfully covered 15,000 information requests on 2,900 substances and compliance dossiers for nearly 3,200 substances in evaluation.[6]

Detailed breakdown of ECHA's role and responsibilities in Section 6.
ECHA Resources in Annex C

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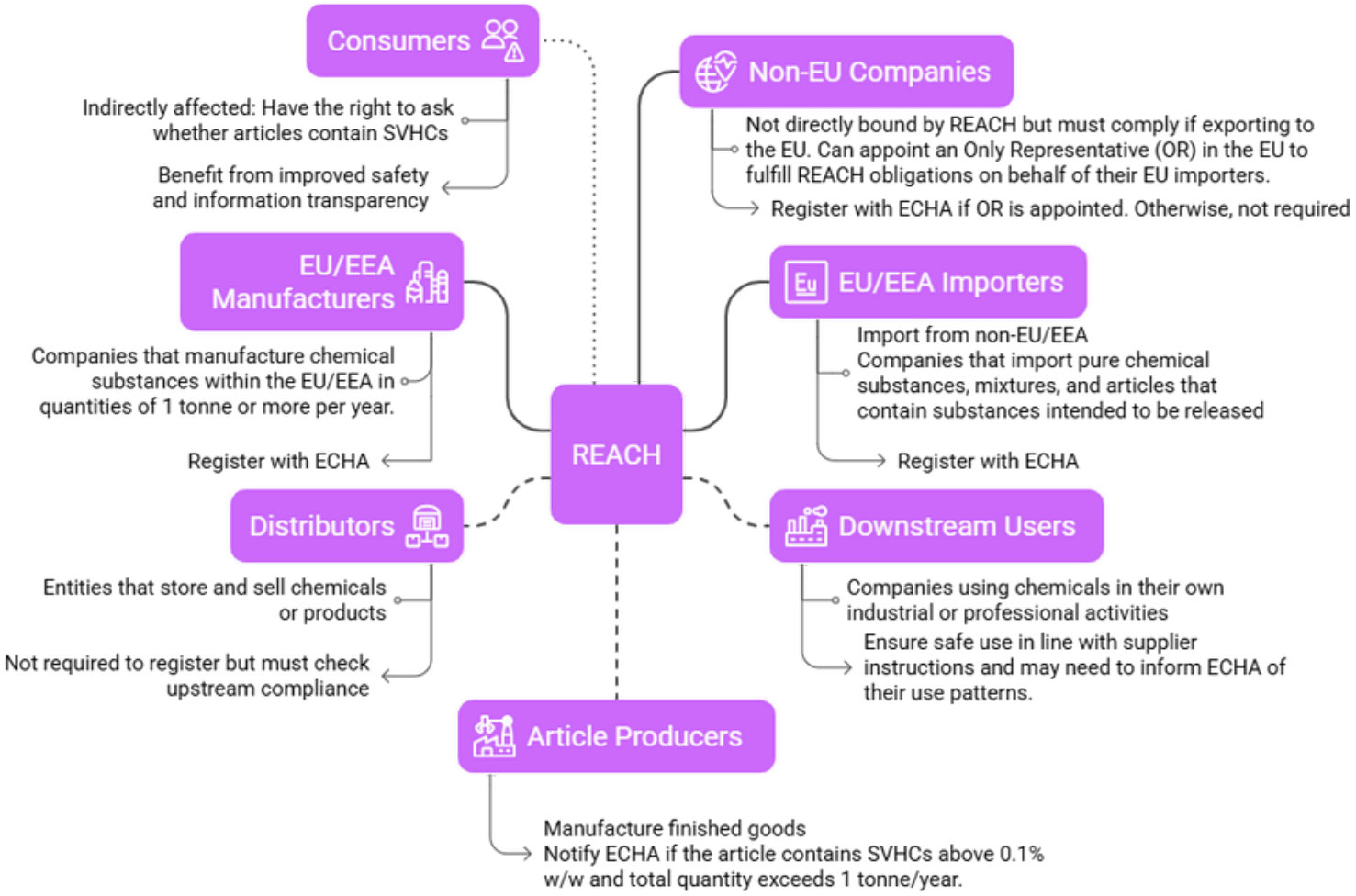
5. European Chemicals Agency (ECHA). *European Union Website.* Available at: https://echa.europa.eu
6. ECHA, "Progress in Evaluation."

2.3 Who is Affected by REACH?



2.4 Substances Covered and Exemptions

Substances Covered

REACH applies broadly to all chemical substances, whether used in industrial processes or in everyday products such as cleaning agents, paints, clothing, furniture, and electrical appliances. However, not all substances fall under the same obligations, and various exemptions are provided based on the substance type, use, or tonnage.

REACH covers:

1. Substances on their own (e.g., ethanol, formaldehyde)
2. Substances in mixtures/preparations (e.g., paints, adhesives, detergents)
3. Substances in articles (e.g., chemicals in furniture coatings, phthalates in plastics)

To be covered by REACH, the substances must be manufactured or imported in quantities of 1 tonne or more per year per legal entity within the EU/European Economic Area (EEA) and should not be already fully regulated under other EU frameworks.

Substances of Very High Concern (SVHCs)
Article 57

Carcinogenic, Mutagenic or Reprotoxic substances (CMRs)[7]
These are substances that can cause cancer, genetic mutations, or harm to reproductive health.

Persistent, Bioaccumulative and Toxic (PBTs)[8]
These are chemicals that remain in the environment for a long time, build up in living organisms, and are harmful to aquatic life or the broader ecosystem. They are difficult to eliminate from the environment and may cause long-term damage to biodiversity and food chains. Their persistence and bioaccumulative nature make their toxicity more significant over time.

Very Persistent and Very Bioaccumulative substances (vPvBs)[9]
These substances share similar properties with PBTs but meet even stricter thresholds for persistence and bioaccumulation. Although they may not be immediately toxic, their long-term presence and accumulation in organisms raise significant concerns for environmental health.

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7. European Commission, "CMR Substances."
8. Toxic-Free Future, "Persistent, Bioaccumulative and Toxic Chemicals."
9. RISCTOX – ISTAS, "PBT and vPvB Substances."

Exemptions

Total Exemptions (Fully excluded from REACH scope):

1. Radioactive substances
Covered under Council Directive 96/29/Euratom

2. Substances under customs supervision
(i.e., those in transit, temporary storage, or in free zones for re-export)

3. Non-isolated intermediates
Chemicals that are produced and consumed in a chemical process without being removed from the equipment

4. Waste
As defined by Directive 2006/12/EC, since waste is not considered a substance or article under REACH

5. Substances used in defence
Member States may exempt substances where necessary for national defence

Special Exemptions

Articles (finished goods)
Producers/importers of articles must register substances that are:
1. Intended to be released under normal use (e.g., fragrance from air freshener)
2. Present as SVHCs ≥0.1% (w/w) and in quantities of ≥1 tonne/year

Notification is not required if:
1. No exposure occurs in intended use
2. The substance has already been registered for that use

Conditional or Partial Exemptions:

1. Polymers
Not subject to registration at present but monomers and additives may require registration

2. Product and Process Oriented Research and Development (PPORD)
Substances used exclusively for R&D can benefit from a 5-year registration exemption, extendable to 10 years. Notification to ECHA is mandatory before use begins Must be handled in controlled conditions and not placed widely on the market.

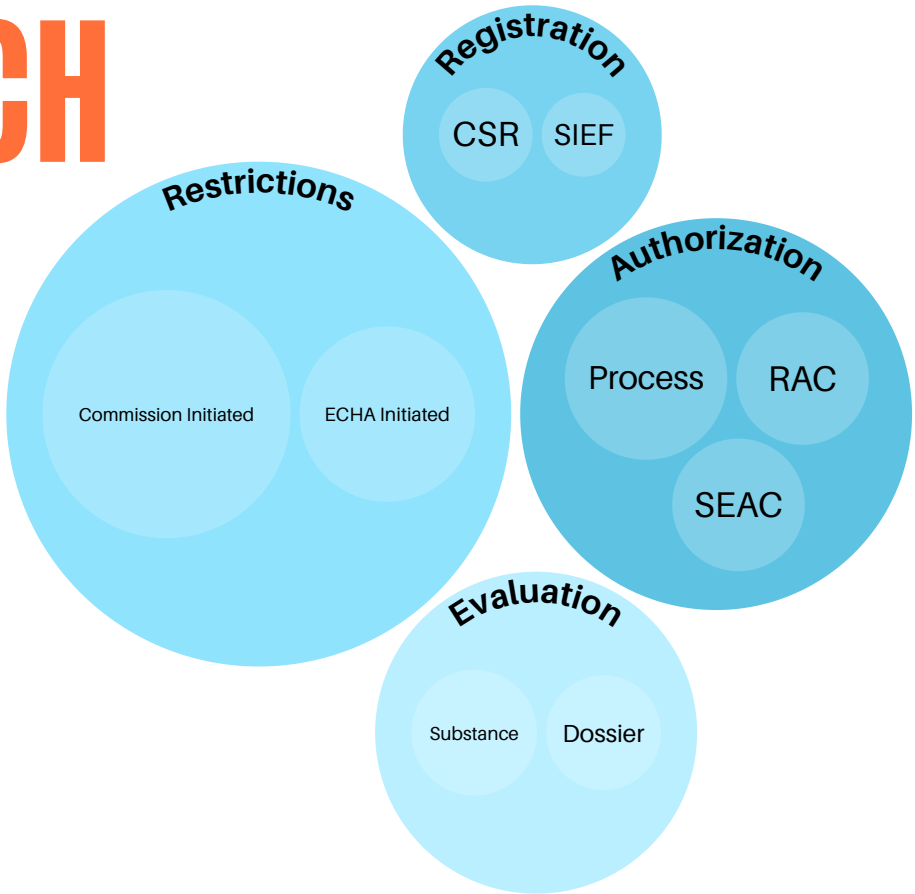
3. Substances already registered and used in specific ways
If substances are used in food or cosmetics, they may be governed by other legislation (e.g., EU food law or Cosmetics Regulation), and therefore some REACH provisions (like CSA) may not apply.

4. Substances used in very low concentrations
In mixtures, substances below 0.1% weight-by-weight (w/w) may be exempt from some requirements (e.g., SVHC notification), unless otherwise specified.

5. Isolated intermediates (transported or on-site)
May benefit from reduced data requirements under certain conditions. Still subject to registration but with simplified dossiers.

6. Recycled or recovered substances
If the substance was already registered and is reused, exempt from re-registration, provided information on its prior registration is available.

3. CORE COMPONENTS OF REACH



3.1 Registration

Registration is the first provision of the REACH Regulation. It ensures that manufacturers and importers take responsibility for understanding and managing the risks associated with the substances they produce or bring into the EU market. Without registration, substances cannot be legally manufactured or marketed in the EU/EEA.

Who Must Register?

Any manufacturer or importer established in the EU/EEA who produces or imports a substance in quantities of 1 tonne or more per year per legal entity must register it with the ECHA. Non-EU companies may appoint an Only Representative (OR) to fulfill these duties.

The OR is required to have technical knowledge on the substances, data on quantity imported and customers, and safety data sheet (SDS). The non-EU manufacturer has to inform importers within the same supply chain that they now fall under downstream users category.

What Must Be Registered?

- Substances on their own
- Substances in mixtures (e.g., solvents, adhesives)
- Substances intended to be released from articles (e.g., ink in pens, fragrance in air fresheners)

Note: Certain substances may be exempt (e.g., waste, radioactive materials, non-isolated intermediates). See Section 2.4 for details.

Registration Dossier Requirements

Registrants must submit a comprehensive technical dossier to ECHA using IUCLID software. The contents vary depending on the annual tonnage band:

Tonnage (per year)	Data Requirements
1 – 10 tonnes	Annex VI + VII (basic info)
10 – 100 tonnes	Annex VI–VIII (extended toxicology & ecotoxicology)
100 – 1000 tonnes	Annex VI–IX (chronic effects, long-term data)
>1000 tonnes	Annex VI–X (full dataset including reproductive toxicity etc.)

Please note that the annexures referred above belong to the orginal legal REACH act

Chemical Safety Report (CSR)

A CSR is also required for substances ≥10 tonnes/year. It includes a Chemical Safety Assessment (CSA) covering:

- Human health hazards
- Environmental hazards
- Physico-chemical hazards
- PBT/vPvB assessment
- Exposure scenarios for each identified use
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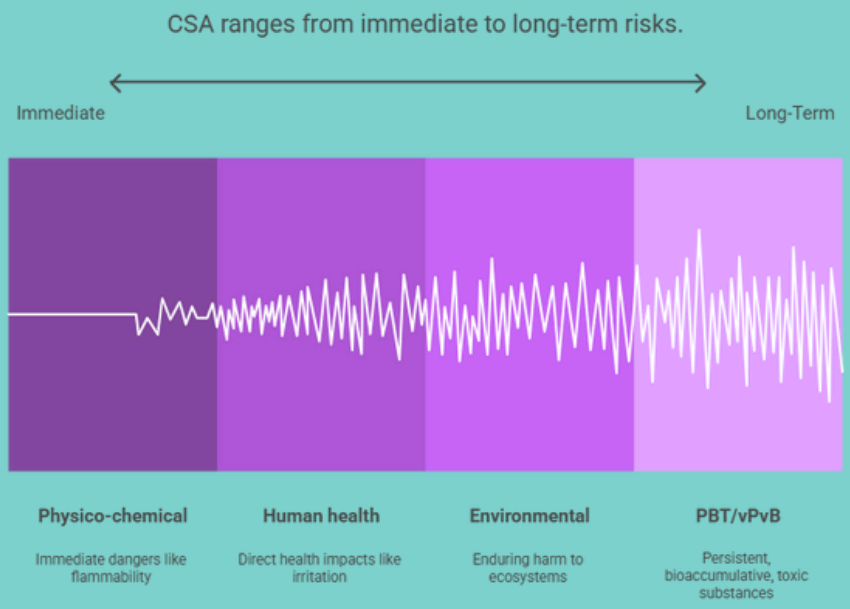
If the CSA identifies a substance as hazardous, the registrant must also perform an exposure assessment and risk characterization.



Joint Registration and SIEF

To avoid duplication of tests—particularly animal testing—REACH promotes joint submissions via Substance Information Exchange Forums (SIEFs). Companies registering the same substance must designate a lead registrant and share data and testing costs fairly. The lead will submit core information on classification and labelling, guidance on safe use, study summaries, SDS, proposal for testing (if needed) and any justification for data waiving or adaptation. Whereas, each registrant individually submits their identity, substance identity, manufacturing/use details and signature.

Registrants may opt out of joint submission if the joint submission is disproportionately costly, it raises commercial confidentiality concerns or there is a scientific disagreement. However, even when opting out, registrants must justify their decision and still submit the required data.

What is the regulatory timeline for registration processing?

After dossier submission, ECHA has 3 weeks to complete the initial completeness check. If deficiencies are identified, a single deadline for correction is given. Once complete, no formal approval is issued, but a registration number is assigned, allowing the substance to be legally placed on the market.

Where applicable, testing proposals and evaluation steps extend timelines to 180 days or more, especially for non-phase-in substances requiring assessment under.

Phase-In vs Non-Phase-In Substances

If a company notified a chemical substance under Directive 67/548/EEC (the law that existed before REACH), that notification is automatically considered a REACH registration.

Phase-in substances: Existing substances registered under earlier laws or pre-registered under REACH deadlines
Non-phase-in substances: New chemicals not previously registered — require pre-inquiry with ECHA to identify existing data holders

SVHC Notification for Articles

Producers or importers of articles must notify ECHA if:

- The article contains a SVHC listed on the Candidate List*
- The substance is present in quantities ≥1 tonne/year AND in concentrations ≥0.1% w/w

Notification is not required if the producer can demonstrate no exposure under normal or reasonably foreseeable conditions of use.

Animal Testing and Alternatives

Animal testing is strongly discouraged under REACH. Companies must use alternatives whenever possible, including:

- In vitro methods
- QSAR models
- Read-across techniques
- Use of existing study data

If testing is required, it must comply with Good Laboratory Practice (GLP) standards** and ethical guidelines.

Updates and Maintenance

Registration is a continuous process. Registrants are legally obliged to keep their dossiers up to date, especially when:

- There is a change in tonnage band, composition, or use
- New hazard data emerges
- Classification or labelling changes
- New uses are identified or withdrawn

Failure to update a registration may lead to enforcement action.

*It is a publicly available list of substances that have been identified as SVHCs and may be subject to future authorization under the REACH Regulation.
** GLP is an OECD-developed system from the late 1970s that ensures the quality and reliability of non-clinical studies used in regulatory submissions.

Frequently Asked Questions

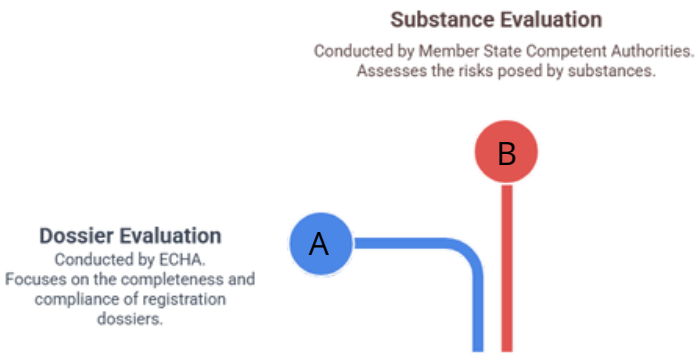
What is a Substance Information Exchange Forum (SIEF) and what is its regulatory function?
A SIEF is a temporary data-sharing mechanism established under Article 29 of REACH to facilitate joint submission of information for identical phase-in substances. All potential and actual registrants, data holders, and ORs for a given substance are required to cooperate within the SIEF to exchange existing studies, avoid unnecessary animal testing, and fulfill data requirements collectively.

Must non-EU manufacturers or exporters register substances under REACH?
No. Legal responsibility for registration lies with the EU-based entity importing the substance. However, under Article 8, a non-EU manufacturer may appoint an OR to assume full registration obligations on behalf of all EU importers. The OR must have sufficient expertise in REACH compliance, access to import volumes, substance identity data, and the ability to compile and maintain SDS.

For information on a specific substance: https://chem.echa.europa.eu/
It is the official portal of the ECHA, providing access to information on chemicals regulated under EU laws like REACH and CLP.

3.2 Evaluation

Evaluation is the second provision of REACH and serves as a critical control mechanism to verify the quality and adequacy of data submitted by registrants. It ensures that information requirements under the Regulation are met and identifies whether additional data is necessary to assess potential risks associated with a substance.



A. Dossier Evaluation

Completeness Check

Upon submission, ECHA performs a completeness check within 3 weeks to verify that:

- All required sections of the IUCLID dossier are completed. It is digital file that registrants (manufacturers or importers) prepare and submit using the IUCLID software to comply with REACH's registration obligations.
- Payment of fees has been made
- Test proposals (where required) are included

If the dossier is incomplete, ECHA will notify the registrant and set a single deadline for corrections. If deficiencies are not resolved, the submission is rejected, and the substance cannot be legally placed on the market.

Compliance Check

Under Article 41, ECHA conducts in-depth compliance checks to assess whether:

- The substance identity is accurately described
- The classification and labelling are justified
- Study summaries meet information requirements
- Waivers or adaptations (under Annex XI) are scientifically sound

ECHA may issue a draft decision. This is shared with the relevant Member States and the registrant(s), who are given 30 days to comment. If Member States suggest amendments, the matter is referred to the Member State Committee (MSC). If no consensus is reached, the European Commission issues the final decision.

Evaluation of Testing Proposals

If a registrant proposes a new test—particularly one involving vertebrate animals—ECHA must evaluate and approve the necessity and design before the test is conducted (Article 40). The Agency:

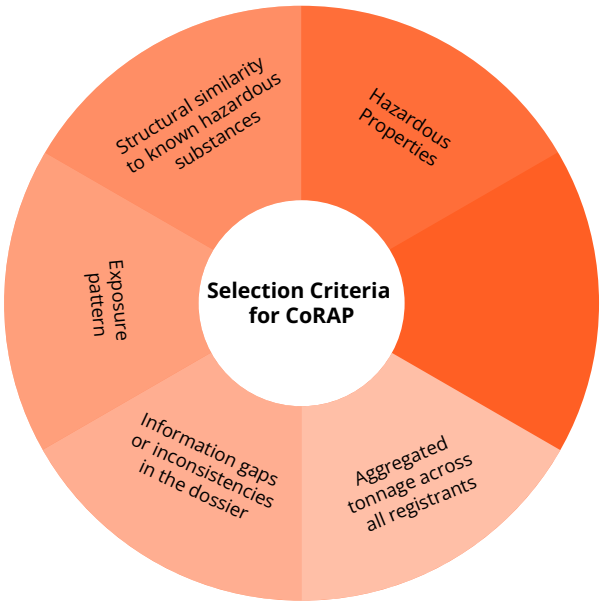
- May modify or approve the test plan
- Consolidates testing requests to avoid duplication
- Prioritizes Substances of Very High Concern (SVHCs)

A formal decision is issued with a deadline for the registrant to submit the test results.

When is there a need for substance evaluation?

Substance Evaluation under REACH is carried out by the Member States' Competent Authorities (MSCAs). It is designed to investigate concerns arising from potential risks to human health or the environment that cannot be resolved through a standard dossier check. These concerns may relate to:

- PBT/vPvB characteristics
- Widespread or significant exposure
- Aggregated use across sectors
- Inconclusive or conflicting data



Community Rolling Action Plan (CoRAP)

Each year, ECHA publishes a Community Rolling Action Plan. A list published and updated annually by ECHA in consultation with Member States. It covers a 3-year window of substances selected for substance evaluation. It identifies the evaluating Member State responsible for each substance. The selection is based on risk-based prioritization that is based on intrinsic hazard properties, exposure data and high-volume use.

Evaluation Process

Once a substance is included in the final CoRAP list, the designated MSCA must begin its evaluation within 12 months of the list's publication.
The process may include:

- Review of registration dossiers
- Use of public information, previous evaluations, and monitoring data

If existing data is insufficient to clarify the risk, the MSCA may draft a decision under Article 46 requesting:

- New test data
- Clarifications on exposure scenarios
- Repeated studies if prior ones are flawed or non-compliant

This draft is submitted to the ECHA, which then circulates it to the concerned registrants and all EU Member States. Registrants are given 30 days to provide comments or objections. If any Member State proposes amendments to the draft during this consultation, the matter is referred to the Member State Committee (MSC) for review.

The MSC seeks to reach unanimous agreement on the decision within 60 days. If such agreement is achieved, the decision is formally adopted by ECHA and becomes legally binding on the registrants. However, if the MSC fails to reach consensus, the matter is escalated to the European Commission. In such cases, the Commission assesses the scientific basis and stakeholder input, and then issues a final, legally binding decision under the comitology procedure.

Read Further:

Official ECHA Guidance for Registrants

For a detailed, step-by-step walkthrough on how to respond during the substance evaluation process, consult:
Registrant's Guide: How to Act in Substance Evaluation
European Chemicals Agency (ECHA), April 2020

Can be accessed online at: https://images.chemycal.com/Media/Files/Manual_Template.pdf

Frequently Asked Questions

Can a substance be subject to both dossier evaluation and substance evaluation?

Yes. A substance may undergo dossier evaluation (for example, to assess the validity of waivers or test proposals) and subsequently be selected for substance evaluation under CoRAP if broader risk concerns exist that are not addressed in the registration.

Can substance evaluation lead to a substance being added to Annex XIV or XVII?

Yes. If the evaluation identifies a serious risk to human health or the environment, the evaluating MSCA may recommend the substance for inclusion on the Candidate List (Annex XIV) or propose a restriction under Annex XVII. These follow separate regulatory procedures but are often triggered by findings from substance evaluation.

3.3 Authorization

Authorization is the third provision under REACH, it is designed to ensure that continued use of SVHCs is allowed only when socio-economic benefits outweigh the risks and no suitable alternatives exist. The EC shall be responsible for taking decisions on applications for authorizations based on the opinion of ECHA.

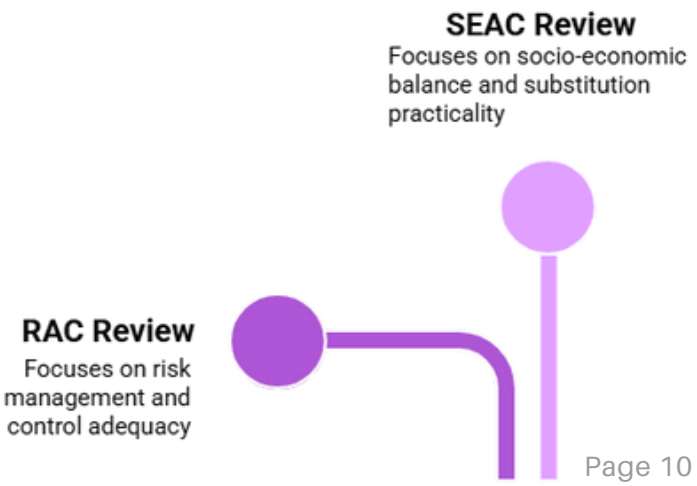
1 **Identify SVHCs** →	**Add to Candidate List** Added to the Candidate List for authorization after public consultation and Member State Committee agreement.	**Prioritize for Annex XIV** ECHA prioritizes from the Candidate List for inclusion in Annex XIV (the Authorization List) based on volume, use, and risk profile.	**Set LAD and Sunset Date** EC sets: Latest Application Date (LAD): By this date, applications for authorization must be submitted Sunset Date: After this date, the substance cannot be used or placed on the market without an authorization. ↓
Notify ECHA Downstream users whose uses are covered by an authorization must notify ECHA of their use within 3 months	**Commission Decision** The EC decides whether to grant or refuse authorization. Authorizations are granted with specific conditions and review periods.	**Public Consultation** ECHA's Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) evaluate the application. Public consultation is conducted on alternatives and societal impacts.	**Submit Application for Authorization** Companies submit authorization applications via REACH-IT. Applications must include Chemical Safety Report (CSR), Analysis of Alternatives (AoA), Substitution Plan, and Socio-Economic Analysis (SEA).
Legal Ban If no application is submitted or the application is refused, a legal ban on the unauthorized use or placing on the market is enforced after the sunset date.			

Committees Involved in Evaluation

The assessment of authorization applications is carried out by two independent expert committees within ECHA. The opinions are typically delivered within 10 months of the application being deemed complete.

Risk Assessment Committee (RAC)

The RAC evaluates whether the risks to human health or the environment from the use of the substance are adequately controlled, in accordance with Article 60(2) of REACH. If adequate control cannot be demonstrated, RAC assesses whether the use poses an unacceptable risk. The committee examines the Chemical Safety Report (CSR), exposure scenarios, and proposed risk management measures.



Socio-Economic Analysis Committee (SEAC)
SEAC assesses whether the socio-economic benefits of the continued use outweigh the risks, particularly in cases where adequate control is not demonstrated. The committee evaluates the applicant's Socio-Economic Analysis (SEA), which must provide detailed cost-benefit assessments, market impact, employment implications, and the feasibility of alternatives. SEAC also examines the Analysis of Alternatives (AoA) and determines whether safer substitutes are technically and economically viable.

Decision Making

When assessing whether to grant authorization, the Commission considers the risks posed by the substance, socio-economic benefits of its use, whether there are suitable alternative. If the risk is not adequately controlled and there are suitable alternatives, authorization is usually refused. Registrants cannot use or sell an Annex XIV substance unless they or someone in their supply chain has obtained authorization or they are covered by one of the clearly stated exceptions. The burden of proof lies on the applicant to demonstrate either adequate control or that socio-economic benefits justify continued use despite the risk. Authorization is not indefinite; it is subject to review periods to encourage substitution over time. Furthermore, the substance can be removed if it can be proved that it is no longer hazardous.

The Candidate List

It is a publicly accessible list maintained and regularly updated by the ECHA. The Candidate List identifies chemical substances that have been recognized as particularly hazardous to human health or the environment. The inclusion of a substance on the Candidate List is a formal signal that it is under close regulatory scrutiny and could eventually be subjected to further restrictions or authorization requirements.

The Candidate List immediately triggers several legal obligations for companies within the supply chain. For example, manufacturers and importers of articles are required to notify ECHA if their products contain substances from the Candidate List in concentrations greater than 0.1% w/w and if the total quantity of that substance exceeds one tonne per year per producer or importer. Additionally, suppliers must inform downstream users and consumers about the presence of these substances in articles and mixtures, and they are required to provide sufficient information to ensure the safe use of the products, free of charge, within 45 days of receiving a consumer request.

The Candidate List is updated at least twice a year following scientific review, Member State proposals, and public consultation.

Frequently Asked Questions

How is a substance added to the Candidate List of Substances of Very High Concern (SVHCs)?
A substance is added to the Candidate List when a Member State or ECHA identifies it as a SVHC based on its hazardous properties, such as being carcinogenic, PBT, or an endocrine disruptor. The proposal is submitted with scientific evidence, followed by a 45-day public consultation. The MSC then reviews the proposal. If there is unanimous agreement, the substance is added to the list. If not, the European Commission makes the final decision.

Does inclusion in the Candidate List automatically restrict the use of a substance?
No. A substance's inclusion in the Candidate List does not immediately prohibit its use or require authorisation. However, it does impose supply chain communication obligations and may require notification to ECHA.

When must companies apply for authorisation to continue using a listed substance?
Companies must submit their application for authorisation before the LAD specified in Annex XIV for that substance.

Can multiple companies submit a joint application for authorisation?
Yes. Joint applications are allowed and often encouraged when companies intend to use the same substance for similar purposes.

3.4 Restriction

Restriction is the fourth provision of REACH. It is the other risk management measure used to protect human health and the environment from unacceptable risks posed by certain substances, mixtures, or articles. Unlike authorization, which controls specific uses of SVHCs, restriction can limit or ban the manufacture, use, or placing on the market of a substance for the entire EU market.

The restriction process under REACH, governed by Title VIII, aims to promptly address chemical risks that are not adequately controlled by prohibiting or limiting substances that pose those unacceptable risks. These restrictions apply uniformly across the EU to ensure consistent protection and fair market conditions. All restricted substances are listed in Annex XVII of REACH, along with their specific or general limitations.

Scope of Restriction

Importantly, restriction can address any substance, including those not classified as SVHCs.

Registration Dossier

Commission-Initiated Dossier

When the EC identifies a risk—arising from new data, incidents, or reports—that is not adequately managed, it may take action by requesting the ECHA to prepare a restriction dossier in accordance with Annex XV.

ECHA-Initiated Dossier

ECHA, on its own initiative, may evaluate post-sunset date use in articles and decide to prepare a dossier

Annex XV format

This dossier includes comprehensive information on the identified risks, potential exposure, and possible options for restriction.

When is Restriction Preferred Over Authorization?

Restrictions apply broadly and are not subject to individual permits—once in place, all companies within the EU/EEA must comply, without the option to seek continued use through authorization.[10]

REACH employs restrictions to eliminate unacceptable chemical risks at the systemic level, while authorization enables continued, controlled use of SVHCs when justified and on a path to substitution, with industry bearing the evidentiary burden. Cases that call for restrictions:

1. When risks cannot be adequately controlled.
2. When there is a need to protect the general public or the environment from widespread exposure.
3. When rapid action is required, such as in cases of emerging chemical threats.
4. When authorization would not cover the relevant uses, such as imported articles.

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10. REACHLaw Ltd., "Authorisation vs. Restriction."

Process

Step	Key Actors	Key Content/Action	Timeline
Preparation of a proposal	EC ECHA	1.If uncontrolled risk from a substance is identified, the EC can request ECHA to draft an Annex XV dossier. or ECHA, after the Annex XIV sunset date, must evaluate continued use in articles. If ECHA concludes the risk isn't adequately controlled, it prepares an Annex XV restriction dossier 2. The dossier must include: substance identity, hazard/risk information, justification, and proposal for restriction.	Dossier preparation must be completed within 12 months of the Commission's request.
Submission and checking of dossiers	ECHA	1. ECHA checks whether the Annex XV dossier is conforming with format and completeness requirements. 2. If not conforming, ECHA informs the submitting party and stops the restriction process.	30 days from dossier submission to complete conformity check.
Public consultation	ECHA Stakeholders (e.g. industry, NGOs, Member States)	1. ECHA publishes the conforming dossier on its website. 2. Opens a 6-month public consultation on the proposed restriction. 3. Stakeholders submit comments on: scientific evidence, socio-economic impact, availability of alternatives, etc.	6 months public comment period.
Committee opinions	RAC SEAC	RAC and SEAC provide opinion. Both may request additional information.	RAC: within 9 months of consultation start. SEAC: within 12 months of consultation start.
Commission decision	EC REACH Committee (Member States)	1. After reviewing committee opinions, the Commission prepares a draft restriction decision. 2. The draft is reviewed. If adopted, the restriction is added to Annex XVII.	No fixed timeline, but follows promptly after SEAC opinion.

Examples of Restricted Substances

Since 2009, according to ECHA, 77 substances have been restricted.[11]

Complete Ban

- DecaBDE (Articles) Banned
- Nonylphenol ethoxylates (NPEs) (Textiles) Use restricted to limit environmental release
- Phthalates (Toys) Use prohibited above specific limits
- Lead (Jewellery) Restricted concentration

Limited Use

Frequently Asked Questions

How is restriction different from authorisation?

Authorisation controls the use of specific SVHCs by requiring prior permission for continued use. In contrast, restriction can apply to any substance, regardless of SVHC status, and can impose complete bans, concentration limits, or specific use conditions across the entire EU market. Restriction is often used for broad public or environmental protection.

Who can propose a restriction?

Restriction proposals can be submitted by EU Member States or by ECHA at the request of the European Commission. The proposal must be supported by an Annex XV dossier that demonstrates an unacceptable risk to health or the environment.

Can restriction apply to imported articles?

Yes. Unlike authorization, restriction can apply to substances in imported articles, ensuring that hazardous substances cannot enter the EU market through imported goods if they are covered by a restriction under Annex XVII.

4. SAFETY AND RISK COMMUNICATION

Under REACH, the safe use of chemicals is supported by open information sharing and risk communication requirements. These obligations ensure that manufacturers, importers, downstream users, and consumers are properly informed about the hazards, safe handling, and regulatory status of substances. The main communication tools are SDS, classification and labelling requirements, and the SIEF.

REACH COMMUNICATION TOOLS

Safety Data Sheets (SDS)	Comprehensive documents detailing chemical properties and safety measures
Classification and Labelling	Standardized symbols and labels indicating hazards and safe handling
Substance Information Exchange Forum	Platform for sharing information and coordinating efforts among stakeholders

11. ECHA, "Substances Restricted under REACH."

4.1 Safety Data Sheets (SDS)

The SDS is the primary document for communicating health, safety, and environmental information about substances and mixtures throughout the supply chain. It ensures that all professional users have access to essential hazard and risk management information.

Requirements

- SDS must comply with Annex II of REACH and follow the 16-section format as outlined in Regulation No 2020/878*. For section-wise breakdown, see Annex D.
- SDS must be provided free of charge to downstream users and distributors.
- The SDS must be supplied:
    1. When a substance is classified as hazardous
    2. When a substance is a PBT, vPvB, or an SVHC
    3. When mixtures contain hazardous components above specified thresholds

Updates

Suppliers must update the SDS without delay if new information on hazards or risk management becomes available, authorization is granted or refused, or new restrictions are imposed.

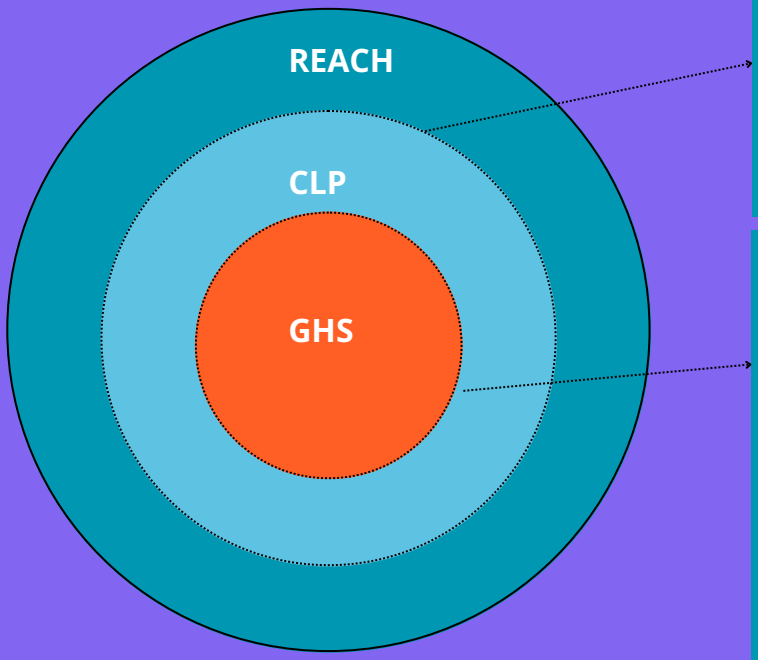
4.2 Classification and Labelling

Under REACH, classification and labelling information must be included in the SDS . The classification and labelling requirements under REACH are fully aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), an international framework developed by the United Nations to standardize chemical hazard communication worldwide. Within the European Union, the CLP Regulation (EC) No 1272/2008 serves as the legally binding instrument that implements the GHS in the EU's regulatory system. Registration dossiers submitted under REACH must contain classification and labelling data consistent with CLP requirements.

Manufacturers, importers, and downstream users must classify their substances and mixtures based on available data. They must label the substances according to their classification and provide the necessary hazard pictograms, signal words, and precautionary statements. Notification to ECHA's Classification and Labelling Inventory is mandatory within one month of placing a classified substance on the market.

Classification and Labelling Inventory

ECHA maintains a central Classification and Labelling (C&L) Inventory, which is a publicly accessible database containing all harmonized classifications, industry self-classifications, and details on labelling and hazard communication.



REACH and CLP

While REACH establishes the framework for chemical registration, risk management, and safety communication, the CLP Regulation specifically governs the classification and labelling process. Compliance with CLP is mandatory for all substances and mixtures placed on the EU market, whether manufactured domestically or imported.

CLP and GHS

Although the GHS provides a globally agreed structure, each jurisdiction, including the EU, determines its own implementation timeline and may adapt some elements based on regional considerations. The EU's CLP Regulation reflects the GHS's structure but is legally enforceable within the European Union.

*Regulation (EU) 2020/878 is a Commission Regulation that amends Annex II of the REACH Regulation (Regulation (EC) No 1907/2006), which outlines the requirements for the compilation of Safety Data Sheets (SDSs).

4.3 Substance Information Exchange Forum (SIEF)

The SIEF is a platform designed to facilitate data sharing, cost-sharing, and communication between companies registering the same substance. SIEFs played a critical role in preventing unnecessary testing, especially on vertebrate animals, and ensured that consistent information was submitted to the ECHA.

Although formal SIEFs were primarily used during the phase-in registration deadlines (2010, 2013, 2018), the principles of joint submission and data sharing established through SIEFs continue to apply under REACH.

Participation in a SIEF was required for all potential registrants of the same substance, companies that pre-registered the substance during the transitional phase-in period, non-registrants holding relevant study data (data holders) and ORs acting on behalf of non-EU manufacturers.

Key Functions of SIEF

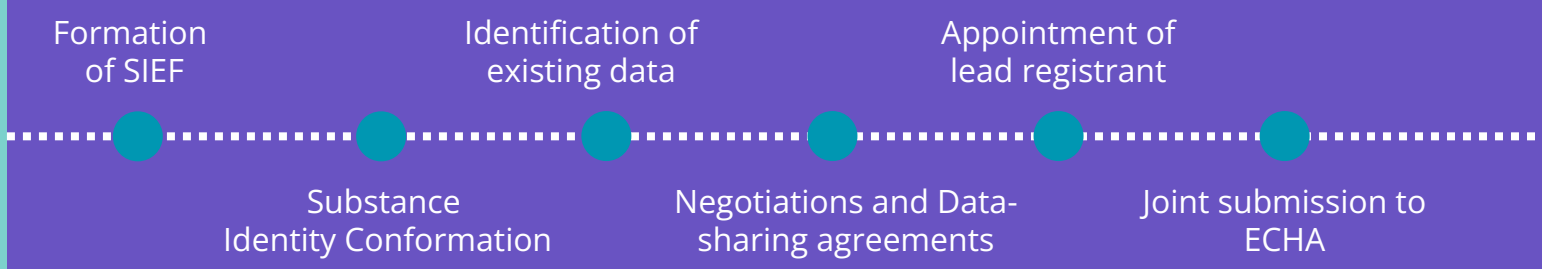
Data Sharing and Negotiation
Companies were required to share existing data and negotiate fair cost-sharing arrangements. Priority was given to avoiding duplicate vertebrate animal tests under Article 25 of REACH.

Identification of Data Gaps
Participants collectively identified missing information and decided on additional studies to be conducted.

Appointment of Lead Registrant
Each SIEF appointed a Lead Registrant, who was responsible for submitting the joint registration dossier on behalf of the group.

Management of Joint Submission
SIEF members submitted individual dossiers but referred to the core shared data provided by the Lead Registrant.

Dispute Resolution
ECHA provided guidance on resolving data-sharing disputes. In cases where no agreement was reached, ECHA could intervene and issue a decision.



Current Status
Ongoing Data and Cost Sharing for New Registrants

5. ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

5.1 Manufacturers

Manufacturers carry the primary regulatory burden under REACH. Without registration, substances cannot be legally manufactured or marketed in the EU.

REGISTRATION	EVALUATION	AUTHORIZATION	RESTRICTION
Must register all substances manufactured or imported in quantities of ≥1 tonne per year. Submit technical dossiers and CSR to ECHA Provide substance identity, hazard information, and intended uses. Update registration dossiers without undue delay if new information on hazards, tonnage, or uses emerges.	Must respond to ECHA's dossier evaluation requests, including providing additional studies or clarifications. Cooperate with substance evaluations initiated under the Community CoRAP.	Must apply for authorization to continue using substances listed in Annex XIV beyond their sunset dates. Ensure that uses in the supply chain are covered by an authorization, if applicable.	Must comply with restrictions outlined in Annex XVII regarding substance manufacture, use, and marketing. Ensure that restricted substances are not used in prohibited applications.

Additionally, they are responsible for preparing and distributing SDS in the correct format to downstream users. They are also required to notify ECHA of hazardous substance classifications for inclusion in the C&L Inventory.

Supply chain Linkage

They must communicate hazard, exposure, and risk management information to importers, distributors, and downstream users and consider downstream user feedback when updating registration dossiers.

5.2 Importer

Under REACH, an importer is legally treated in the same way as a manufacturer located within the EU when it comes to registering substances.

REGISTRATION	EVALUATION	AUTHORIZATION	RESTRICTION
Must register all imported substances ≥1 tonne/year. Fulfil the same technical dossier and CSR requirements as manufacturers. * Responsible for ensuring imported substances comply with REACH, regardless of supplier's location	Must comply with all ECHA requests for additional information or testing. Cooperate in dossier and substance evaluations.	Must ensure that imported substances subject to authorization are either authorized or covered by an existing authorisation.	Must not import substances or articles that are subject to prohibitions under Annex XVII.

*They must either gather this information directly from their non-EU supplier or develop it themselves.

Notify ECHA of classified substances within one month of placing them on the market.

Supply Chain Linkage

Importers must coordinate closely with ORs, non-EU manufacturers, and downstream users to ensure.

5.3 Only Representative (OR)

ORs provides a critical pathway for non-EU companies to access the EU market while retaining control over regulatory compliance.

REGISTRATION	EVALUATION	AUTHORIZATION	RESTRICTION
Registers substances on behalf of non-EU manufacturers. Assumes full importer responsibilities under REACH.	Must comply with all evaluation procedures, data requests, and dossier updates.	Responsible for submitting authorization applications if required by the non-EU principal.	Must ensure that imported substances comply with Annex XVII restrictions

They are also responsible for maintaining accurate records of customer lists and import volumes.

Supply Chain Linkage

ORs essentially serves as the primary compliance contact for both the non-EU manufacturer and EU-based customers.

5.4 Downstream User

Downstream users play a vital role in workplace safety and supply chain compliance but do not typically submit registrations.

REGISTRATION	EVALUATION	AUTHORIZATION	RESTRICTION
No direct registration obligation unless acting as a manufacturer or importer.	Must provide use information to upstream suppliers to ensure it is covered in the registration. May need to submit a CSR to ECHA if their use is outside the supplier's registered scenarios.	Must ensure that their use of Annex XIV substances is covered by an existing authorization. Must notify ECHA within three months of first use of an authorized substance.	Must comply with all restrictions on the use and marketing of substances and mixtures.

Additionally, they must implement all risk management measures outlined in SDS, communicate new uses or safety information to suppliers, and ensure safe workplace practices in line with chemical safety assessments.

Supply Chain Linkage

Downstream users are highly dependent on upstream hazard communication and are obliged to inform suppliers about specific uses and feedback on safety data.

5.4 Distributor

Distributors are not typically data generators but are essential for maintaining hazard communication integrity.

REGISTRATION	EVALUATION	AUTHORIZATION	RESTRICTION
No registration obligation unless the distributor is also an importer.	No direct evaluation obligations.	Must ensure that substances subject to authorization are appropriately authorized before being distributed.	Must comply with all restrictions on substances they distribute.

Distributors have to pass on accurate labelling and SDS without altering safety information.

Supply Chain Linkage

They act as a conduit for hazard communication between manufacturers/importers and downstream users.

5.4 Non-EU Countries

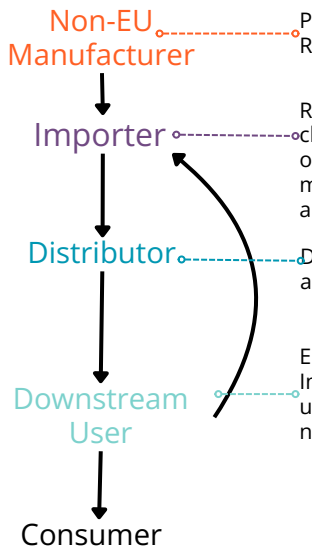
Companies located in any non-EU country cannot directly register substances under REACH because REACH is an EU-specific regulation. However, non-EU companies that want to sell their substances, mixtures, or articles in the European market must ensure that their products comply with REACH through designated pathways.

REGISTRATION	EVALUATION	AUTHORIZATION	RESTRICTION
Non-EU manufacturers cannot directly register substances under REACH. They can access the EU market by appointing an OR or by supplying through an EU-based importer who will take on full REACH registration responsibilities. If using an OR, the non-EU manufacturer must provide the OR with all relevant substance identity, hazard, and usage data required for registration.	Non-EU companies themselves are not directly involved in REACH evaluations. Their appointed OR or importer will handle ECHA's evaluation requests, provide additional data if needed, and manage dossier updates. However, the quality of the data provided by the Non-EU company significantly impacts the success of the evaluation process.	If the substance is subject to authorization (Annex XIV), the OR or EU importer must apply for authorization on behalf of the non-EU manufacturer to continue using or placing the substance on the EU market. Non-EU manufacturers must support this process by supplying hazard data, exposure scenarios, and socio-economic information as required.	Substances subject to restriction under Annex XVII cannot be imported into the EU in contravention of the restriction limits, regardless of origin. Non-EU manufacturers must ensure that their substances, mixtures, or articles meet all applicable restriction conditions (e.g., concentration limits, use bans).

Furthermore they must provide sufficient hazard and risk data to the Only Representative or importer, comply with all contractual obligations to ensure accurate and complete data transfer and ensure that proper labelling and packaging aligned with the CLP Regulation are applied before the substance enters the EU market.

Supply Chain Linkage

Must cooperate closely with their appointed Only Representative or EU-based importer.



Provides substance, use and hazard information but is not legally responsible for REACH registration.

Registering a substance and conducts self-classification if no harmonized classification exists, notifying ECHA's Classification and Labelling Inventory within one month of first market placement, provides use and hazard information and monitors for updates in hazard data or usage information. Additionally, it ensures all identified uses in the EU supply chain are included in the registration dossier.

Distributes substance, passes on SDS and labels unchanged to downstream users and consumers.

Ensures their use is covered in the importer's registration and exposure scenarios. Implements risk management measures as described in the SDS. Notifies ECHA if using an authorised substance under specific conditions. Must communicate any new use or safety information to the importer for dossier updates.

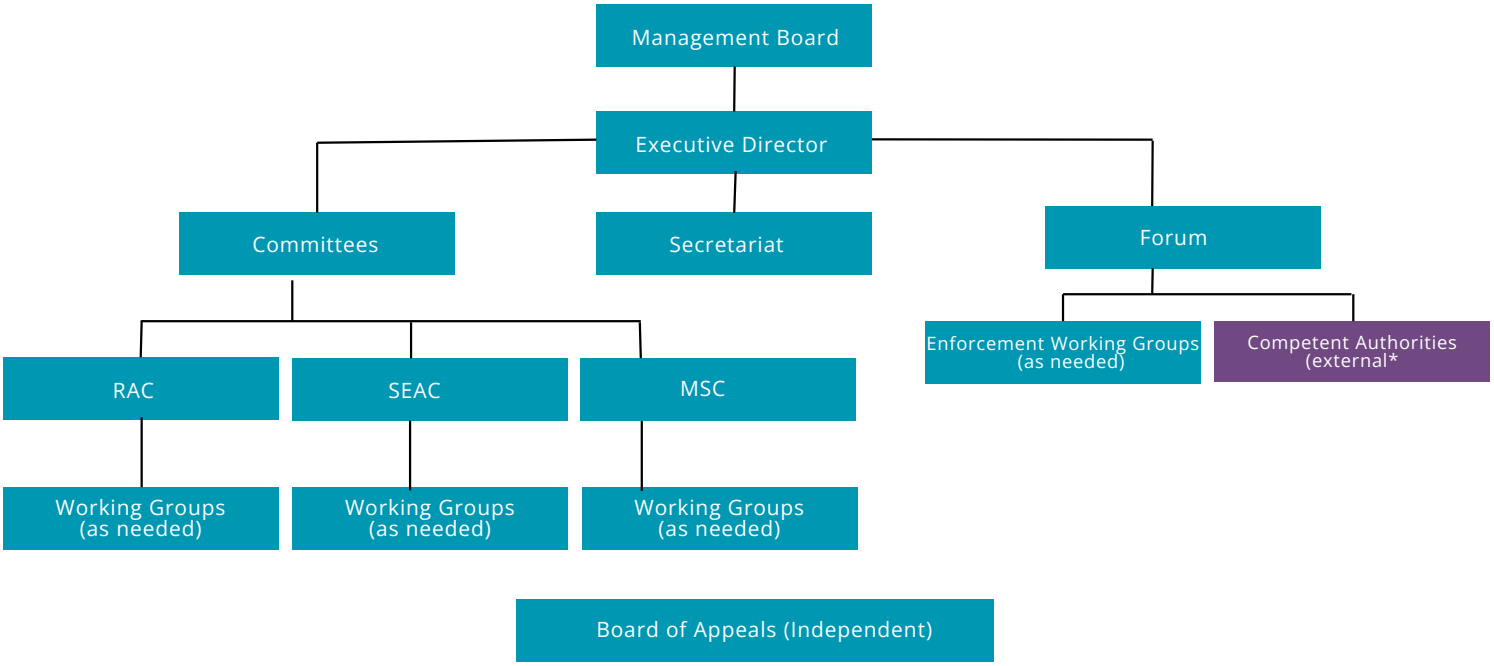
Supply Chain Linkage

6. REGULATORY OVERSIGHT AND ENFORCEMENT

6.1 Role of ECHA and National Authorities

The REACH Regulation is enforced through a combination of centralized EU oversight by ECHA and decentralized enforcement by national authorities within each EU Member State. REACH is unique in that it places the primary compliance burden on companies, but robust regulatory structures are in place to monitor, evaluate, and enforce those responsibilities.

ECHA's Organizational Structure



*National Authorities are external but integral enforcement bodies that operate alongside ECHA's structure, primarily interacting through the Forum for Exchange of Information on Enforcement.

Management Board

The Management Board is responsible for strategic oversight, budget approval, staffing decisions, and ensuring institutional transparency. It adopts the Agency's work programme, budget, and annual reports, and appoints the Executive Director (ED), accounting officer, and members of the Board of Appeal in accordance with REACH. The Board also designates committee members and oversees the annual reporting of evaluation outcomes to uphold accountability.

The Board's composition is structured as such that each EU Member State nominates one representative. The EC may appoint up to six additional members, including three non-voting representatives from industry, civil society, and trade unions. The European Parliament appoints two independent experts. Board members are selected based on demonstrated expertise in chemical regulation, public policy, finance, or legal affairs. Terms are typically four years and may be renewed once.

Executive Director (ED)

The Executive Director serves as ECHA's chief executive, accountable for the day-to-day administration of the Agency. The ED manages operational activities, staff, and resource allocation, and is responsible for the preparation and execution of the Agency's work programme. The ED ensures coordination between ECHA's scientific committees and the Forum for Exchange of Information on Enforcement and determines access protocols for ECHA's digital platforms and tools.

The ED is appointed by the Management Board for a renewable five-year term, following a competitive selection process initiated by the EC. The ED operates under the strategic oversight of the Management Board and maintains regular engagement with the European Parliament.

Committees

ECHA's scientific committees provide technical assessments and regulatory opinions that underpin key decisions under REACH. The RAC delivers independent evaluations of chemical risks, while the SEAC provides impact assessments related to authorizations and restrictions. The MSC resolves divergences among Member States, particularly in substance evaluation.

Committees are composed of Member State nominees and supported by rapporteurs appointed on a case-by-case basis. External experts may contribute through formal working groups. Committee members are selected for their technical competence and are required to act in the public interest, free from conflicts of interest. Committee opinions are adopted by consensus or formal voting procedures and are coordinated under the oversight of the Executive Director. See Annexure D for how these committees are formed

Forum for Exchange of Information on Enforcement

The Forum is the operational platform that facilitates coordination and harmonization of REACH enforcement across EU Member States. It develops best practices, inspection methodologies, and practical tools to support national enforcement bodies. The Forum also organizes EU-wide inspection campaigns and advises on the enforceability of proposed restrictions.

Forum members are nominated by national enforcement authorities and work collaboratively to strengthen regulatory compliance across the internal market. The Forum reports directly to the Executive Director and plays a critical role in ensuring the effective and uniform application of REACH across jurisdictions.

Secretariat

The Secretariat provides essential technical, scientific, and administrative support to all of ECHA's bodies. It manages core ECHA functions, including information systems, document management, communications, and logistical coordination. The Secretariat supports the work of the Committees, the Forum, and the Board of Appeal.

Operating under the direction of the ED, the Secretariat ensures the smooth functioning of the Agency's internal processes and is staffed in accordance with ECHA's human resources policies.

Board of Appeal (BoA)

The Board of Appeal is ECHA's independent judicial body tasked with reviewing appeals against the Agency's decisions, including those related to registration, evaluation, authorization, and data-sharing disputes.

The Board consists of a Chairperson and two members, with designated alternates, appointed by the Management Board based on nominations from the EC. Members are required to demonstrate independence, high professional standing, and freedom from conflicts of interest. Decisions of the Board of Appeal may be further challenged before the Court of Justice of the EU, providing an additional layer of judicial oversight.

Competent Authorities

Each EU Member State designates a national CA to oversee REACH implementation. These authorities are tasked with coordinating enforcement, submitting risk-related data to ECHA, and operating national helpdesks to provide technical guidance to regulated parties. Where public health or environmental risks are identified, competent authorities are obliged to communicate such risks transparently to the public.

CA in each EU Member State are responsible for the direct enforcement of REACH at the national level. They perform market surveillance, conduct inspections, verify company compliance with registration, authorization, restriction, and safety communication requirements, and have the authority to impose administrative penalties, market restrictions, or product recalls in cases of non-compliance.

6.2 Decision-Making in ECHA

Registration & Evaluation Decisions

1. Dossier Submission (Article 10)
2. ECHA Completeness Check & Draft Decision (Articles 20, 40-41)
3. Registrant's Right to Comment (Article 50)
4. Draft Shared with Member States (Article 51)
5. MSC Unanimous Agreement or Escalation to European Commission

(If MSC can't agree → decision moves to Commission)

Authorization Decisions

1. Application for Authorization Submitted (Article 62)
2. Public Consultation on Alternatives (Article 64)
3. RAC and SEAC Issue Draft Opinions (Article 64)
4. Applicant's Right to Comment (Article 64)
5. Final Opinions Sent to the Commission (Article 64)
6. Commission Prepares Final Decision (Article 64)
7. Commission Publishes Decision & Authorization Number (Articles 64, 65)

Restriction Decisions

1. Proposal Preparation by Agency or Member State (Article 69)
2. Public Consultation on Restriction Dossier (Article 69)
3. Opinions by Risk Assessment & Socio-Economic Committees (Article 70)
4. Submission to Commission (Article 71)
5. Commission Decision on Restriction (Annex XVII) (Article 73)

Appeals Process

1. Filing an Appeal (Article 92)
2. Rectification Possible by Executive Director (Article 93)
3. If Not Rectified → Review by Board of Appeal (Article 93)
4. Board of Appeal May Confirm, Amend, or Remit Decision (Article 93)

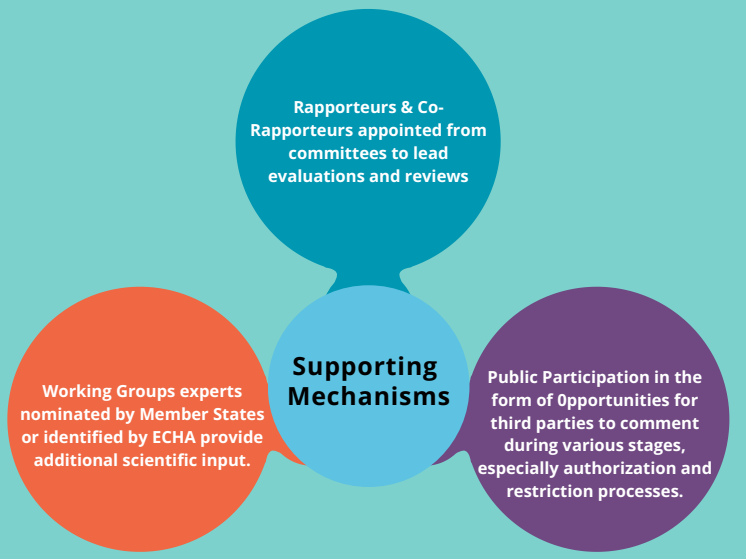
Conflict Resolution with Other Agencies

1. ECHA proactively identifies potential scientific or technical conflicts with other EU bodies.
2. ECHA and the conflicting body must collaborate to resolve the issue or submit a joint report to the Commission clarifying the disagreement. (Article 95)

Example:

Decision-Making Timeline

STEP	TIMELINE
Completeness Check	Immediate upon submission
Comments by registrants	30 days
Member State review of draft decision	30 days
MSC consensus (if needed)	60 days
Authorization Committee opinions	10 months
Applicant comments on draft decision	30 days
Appeal submission	Within 3 months of decision
Rectification by ED	30 days



6.3 Third Party Representation

REACH strictly prohibits non-EU manufacturers from registering substances directly with ECHA. To navigate this, third-party mechanisms ensure that REACH compliance can still be achieved without shifting the entire burden to EU-based importers.

Purpose of Third-Party Representation

Third-party representation is a key feature in the REACH Regulation designed to safeguard confidential business information (CBI), enable companies, particularly non-EU manufacturers and SMEs, to comply with REACH requirements without disclosing sensitive details (e.g., supply chain, substance composition), and facilitate participation in substance information exchange forums (SIEFs), joint submissions, appeals, and authorisation processes through trusted intermediaries.

Who Can Act as a Third-Party Representative?

Any legal or natural person established in the EU. They must be formally appointed by the manufacturer, importer, downstream user, or applicant on act on their behalf.

Roles and Rights of Third-Party Representatives

Communication Hub: Third-party representatives liaise with ECHA, Member State Competent Authorities, and other registrants.

Protection of Identity: They shield the identity of companies involved, especially in joint submissions and substance evaluations.

Participation in SIEFs: They can represent a company in data sharing and cost negotiations within Substance Information Exchange Forums.

Appeals: They may submit appeals and represent clients before the ECHA Board of Appeal, provided proper authorisation.

Legal Considerations

The third-party representative must have a written agreement from the party they represent. The scope of authority should be clearly defined (e.g., registration, appeals, SIEFs).If the representative acts dishonestly or beyond their mandate, the legal liability remains with the registrant or the company represented.

6.4 Legal Recourse and Appeals

The REACH Regulation includes a formal, multi-layered appeal and judicial review system to protect the rights of companies and ensure the ECHA acts within its legal and procedural limits. Companies have the right to challenge ECHA's decisions first within ECHA's internal framework and, if necessary, before the European Union courts.

Decisions Subject to Appeal

Dossier Evaluation Decisions:
E.g., requests for additional studies, testing proposals, or compliance checks.

Substance Evaluation Decisions:
E.g., decisions requiring more hazard or exposure data for specific substances.

Testing Proposal Decisions:
E.g., approvals or rejections of proposed testing methods.

Decisions on Authorization Applications:
E.g., decisions concerning continued use of substances subject to authorization.

Restriction Decisions:
E.g., ECHA decisions that restrict substances based on risk or insufficient control.

Data Sharing Disputes:
E.g., decisions on disputes between registrants regarding data-sharing costs or access.

Appeal Process

Action/Event	Who is Involved	What Happens	Possible Outcomes
ECHA Issues Decision	ECHA	ECHA issues a decision on dossier evaluation, authorization, restriction, or data-sharing disputes.	Company reviews decision.
Company Files Appeal (within 3 months)	Registrant/Company	Appeal submitted to ECHA's Board of Appeal outlining procedural, legal, or scientific grounds.	Appeal accepted for review.
Appeal Reviewed by Board of Appeal	ECHA's Board of Appeal	Independent review of ECHA's decision based on submitted evidence and REACH legal framework.	Decision upheld, annulled, amended, or remitted.
Appeal Decision Communicated	ECHA/BoA	Final decision from the Board of Appeal is formally communicated to the appellant and ECHA updates records.	Process may end here, or company may escalate.
*Further Legal Challenge to General Court (if needed)	Registrant/Company, General Court of the EU	Company files legal action against the Board of Appeal's decision, alleging legal or procedural errors.	Court ruling may uphold or overturn BoA decision.
Optional Appeal to Court of Justice of the EU (CJEU)	Registrant/Company, CJEU	Further appeal on points of law to the CJEU (highest EU court).	CJEU ruling is final and binding.

*Grounds for challenging Board of Appeals decision can be misapplication of REACH, violation of procedural rights, disproportionate or unreasonable decision

7. CROSS-CUTTING CONSIDERATIONS

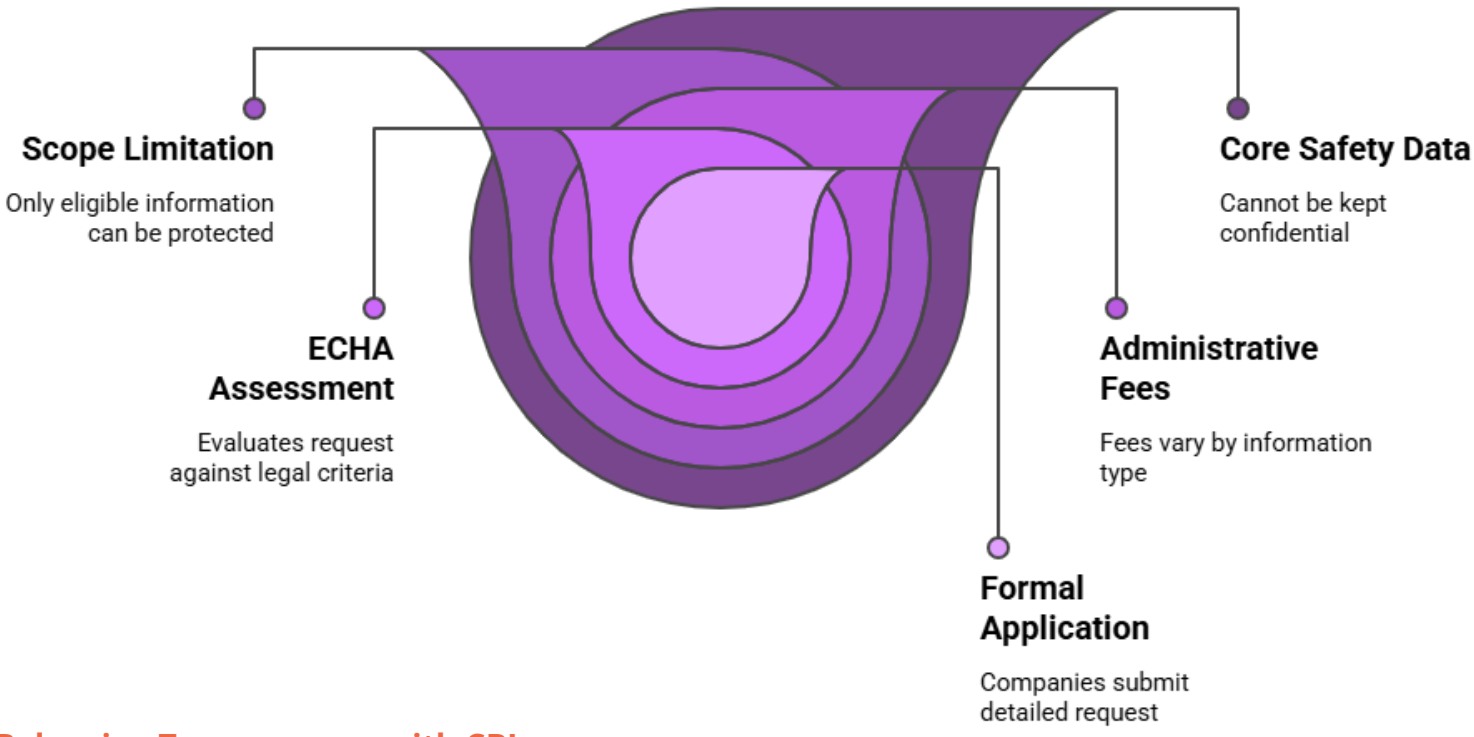
7.1 Confidential Business Information (CBI)

REACH emphasizes the importance of transparency and public access to chemical safety information. However, it also recognizes the need to protect sensitive commercial information that, if disclosed, could harm a company's competitive position. Companies can request certain information to remain confidential by demonstrating that disclosure would likely cause commercial damage. These requests are regulated under Article 119 of REACH and must be individually justified and approved by ECHA.

What Information Can Be Protected as CBI?

1. Identity of the Manufacturer or Importer
2. Exact Tonnage Band
3. Chemical Composition
4. Trade Names and Specific Uses

Procedure for Confidentiality Requests



Balancing Transparency with CBI

REACH is designed to maximize public access to chemical safety data to promote informed decision-making, workplace safety, and environmental protection. And, respect legitimate commercial interests by allowing confidentiality where disclosure would cause measurable harm to a company's market position or intellectual property.

Companies that falsely or improperly request confidentiality may face penalties. CBI protection is not indefinite; ECHA can reassess confidentiality if market conditions or legal interpretations change. ECHA publishes non-confidential summaries of all registered substances on its public database, even if CBI is granted for specific elements.

7.2 Cost Considerations and Fees

Fees are stipulated in Commission Regulation (EC) No 340/2008 and vary according to company size, tonnage band, and the complexity of the substance being registered. These fees are reviewed annually to account for inflation. A portion of the collected fees is allocated to Member States' Competent Authorities to support evaluation activities.

All payments must be made in euros (€). No fee is required for substances registered under 10 tonnes per year, provided the submission includes a complete dossier that fully complies with the information requirements set out in the REACH Regulation.

Registrants must pay the applicable fee within 14 calendar days of the invoice date. For phase-in substances, a payment window of 30 days is granted. If the initial payment deadline is missed, ECHA may issue a second and final deadline before the registration is considered void.

Standard Fees – Individual vs Joint

	Individual Submission	Joint Submission
Substance range 1-10 tonnes	1600	1200
substance range 10-100 tonnes	4300	3225
Substance range 100-1000 tonnes	11500	8625
Substance range above 1000 tonnes	31000	23250

Support for SMEs

In the case of small and medium-sized enterprises (SMEs), a discounted fee will be applied. The tables below outline the definitions of organizations within this category and the registration rates based on them.

	Definition Source	Description
Medium Enterprise	Rec. 2003/361/EC	<250 employees AND either ≤ €50 million turnover OR ≤ €43 million balance sheet total.
Small Enterprise	Rec. 2003/361/EC	<50 employees AND either ≤ €10 million turnover OR ≤ €10 million balance sheet total.
Micro Enterprise	Rec. 2003/361/EC	<10 employees AND either ≤ €2 million turnover OR ≤ €2 million balance sheet total.

	Micro	Micro	Small	Small	Medium	Medium
Substance range 1-10 tonnes	160	120	640	480	1120	840
substance range 10-100 tonnes	430	323	1720	1290	3010	2258
Substance range 100-1000 tonnes	1150	863	4600	3450	8050	6038
Substance range above 1000 tonnes	3100	2325	12400	9300	21700	16275

Similar standard fee structure based on tonnage and organization classification are available for isolated intermediates registration, registration updates, data-requests, PPORD notification and extension, authorization application and review fees, and appeal fees in the annexures of the official document.

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12. Regulation (EC) No 340/2008

7.3 Extra Provisions

SME Support and Flexibility

Small and medium-sized enterprises (SMEs) face unique challenges in terms of regulatory complexity, data generation costs, and administrative burden. To address these barriers, REACH includes structural support mechanisms tailored to SMEs. ECHA operates dedicated SME helpdesks and publishes extensive technical guidance, including step-by-step dossier preparation manuals and IT tool instructions (e.g., for IUCLID[13] and REACH-IT[14]).

Beyond technical assistance, enforcement authorities across Member States may apply proportionality when inspecting or sanctioning SMEs. In practice, this means that SMEs are often given opportunities to rectify errors or omissions before fines or legal penalties are imposed. ECHA also offers manual completeness checks for first-time SME registrants, helping companies avoid costly rejections and maintain access to the EU market.

Innovation and Safer Substitution

REACH acts as a driver for safer chemistry and innovation. One of its most effective innovation pathways is the regulatory pressure it places on companies to substitute SVHCs with safer alternatives. Companies can signal their innovation efforts through substitution plans or participate in authorization applications that outline time-limited use scenarios while alternatives are being developed.

REACH also includes specific exemptions for research and development. Under the PPORD scheme, companies may use unregistered substances in R&D under controlled conditions without undergoing full registration. This exemption is valid for up to five years and may be extended upon request. PPORD notifications must be submitted to ECHA and include sufficient justification for the research purpose and safe use of the substance. These mechanisms enable chemical developers, academic labs, and start-ups to innovate without immediate regulatory cost, provided the activity is confined to research and not commercialization.

Public Awareness and Stakeholder Engagement

To ensure public oversight, ECHA maintains one of the world's most comprehensive chemical safety databases, accessible online. This includes registration data, hazard classifications, exposure information, and regulatory actions for thousands of substances. By publishing this data, REACH allows not only regulators and companies, but also NGOs, consumers, workers' unions, and academia to participate in monitoring chemical risks and evaluating compliance.

Furthermore, stakeholder engagement is embedded into the regulatory process itself. During the identification of SVHCs, development of restriction proposals, or evaluation of authorization applications, REACH mandates formal public consultation periods. These allow stakeholders to submit scientific, technical, and socioeconomic information that could influence regulatory outcomes. The combination of data transparency and consultation mechanisms strengthens the adaptability of REACH decision-making.

Capacity Building for Third Countries

Recognizing the global influence of REACH, the EC and ECHA also support capacity-building initiatives for developing and transition economies. These efforts are particularly targeted at third-country exporters that must comply with REACH in order to access the EU market. Capacity-building activities include training workshops, technical documentation, and the promotion of REACH-aligned national systems. Many exporters from non-EU countries also rely on the services of EU-based ORs to manage their REACH obligations, and ECHA provides tools and guidelines to ensure that ORs can operate effectively and transparently.

These outreach and technical cooperation activities have helped harmonize chemical management systems globally while facilitating compliance for manufacturers in countries where REACH-like regulations are still emerging.

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13. European Chemicals Agency (ECHA, "IUCLID: International Uniform Chemical Information Database."
14. European Chemicals Agency (ECHA), "REACH-IT User Manual."

Institutional Reporting and Monitoring Obligations

Every five years, Member States are required to submit implementation reports to the EC, covering evaluation and enforcement outcomes. Concurrently, the ECHA must report on the overall operation of the Regulation. In line with REACH's commitment to animal welfare and alternative testing, ECHA also submits a triennial report on the development and uptake of non-animal testing methods. The Commission consolidates these inputs into a five-year performance report, which includes an assessment of regulatory impact and the allocation of EU funds for test method innovation. These mechanisms collectively support data-driven policy adjustment and institutional learning.

Enforcement and Compliance Mechanisms

REACH enforcement is decentralized but harmonized through minimum expectations. Member States are required to maintain official control systems, including inspections, monitoring regimes, and penalties proportionate to the nature and severity of non-compliance. National enforcement outcomes are reported every five years. These reports follow a structure agreed upon by the REACH Forum and are shared with both the Commission and ECHA to enable coordinated evaluation and benchmarking of enforcement performance across jurisdictions.

Free Movement and the Safeguard Clause

REACH ensures that compliant products may circulate freely within the EU. However, where Member States identify an urgent risk to human health or the environment, they may invoke a safeguard clause allowing temporary national measures. These must be notified to the Commission, ECHA, and other Member States. Within 60 days, the Commission must either authorize the provisional measure, reject it, or initiate further action. In the event of a proposed restriction, the Member State must submit a formal dossier under Annex XV within three months. This safeguard mechanism maintains regulatory flexibility while preserving the integrity of the internal market.

7.4 Trade Implications

Is REACH a Trade Barrier?

In its current form, the EU's REACH regulation does not constitute a trade barrier under prevailing international trade law. Rather than impeding access to the European market, REACH has in many cases acted as a driver of regulatory alignment, with numerous exporting countries proactively adjusting their domestic chemical safety frameworks to meet EU standards.[15] This trend toward harmonization reflects the regulation's influence as a global benchmark rather than a restrictive measure.

However, concerns persist. Particularly among WTO member states from developing economies, regarding the regulation's complexity, limited transparency, and its potentially disproportionate impact on market access.[16] Notably, REACH's current scope does not apply the same authorization requirements for SVHC to imported articles as it does to domestically produced goods—thereby reducing its immediate external trade impact. Importantly, REACH has so far operated within the normative boundaries of the WTO's Technical Barriers to Trade (TBT) Agreement and has not been subject to any formal disputes.[17]

Looking ahead, however, legal analyses caution that if REACH were to extend authorization requirements to imported articles, such measures could be classified as non-tariff trade barriers under WTO rules.[18]

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15. Cha and Koo, "Who Embraces Technical Barriers to Trade?"
16. WTO TBT Committee, "Minutes, November 2007."
17. Schenten and Führ, "SVHC in Imported Articles."
18. Environmental Sciences Europe, "Extended Authorisation under REACH."

8. INTERNATIONAL CONTEXT

8.1 REACH and UK REACH (Post-Brexit)

Aspect	EU REACH	UK REACH
Jurisdiction	27 EU Member States, plus EEA countries (Norway, Iceland, Liechtenstein)	Great Britain (England, Scotland, Wales) only; Northern Ireland follows EU REACH
Start Date	Jun 1, 2007	Jan 1, 2021
Regulatory Authority	ECHA	HSE, with policy input from DEFRA
Registration Database	ECHA REACH-IT, IUCLID	Separate UK REACH IT system (based on original EU model)
Access to Existing EU REACH Data	Full access within EU system	No automatic access; companies must obtain or renegotiate data rights
Transitional Measures	Not applicable	DUIN (Downstream User Import Notification), Article 127B transitional provisions
Mutual Recognition	Applies across EU/EEA	No mutual recognition with EU REACH
Data Sharing	Required under joint submissions and SIEFs	No link to EU SIEFs; data must be reacquired or re-negotiated
Public Access to Data	Full transparency via ECHA database	Developing separate UK database with similar disclosure intent

UK REACH

Following the United Kingdom's departure from the EU, a parallel regulatory system—UK REACH—was established under the European Union (Withdrawal) Act 2018. UK REACH retains much of the architecture of EU REACH, including registration, authorization, restriction, and evaluation mechanisms. However, it is independently administered by the UK Health and Safety Executive (HSE) and the Department for Environment, Food & Rural Affairs (DEFRA).

Substances registered under EU REACH are no longer automatically recognized in the UK, and vice versa. UK-based registrants must hold UK registrations, and EU-based companies exporting to the UK must appoint a UK-based OR.

For more information:
https://www.hse.gov.uk/reach/index.htm
https://www.legislation.gov.uk/ukpga/2018/16/contents

8.2 REACH and the U.S. TSCA

Aspect	Before 2016	After 2016 Reform	REACH Alignment
Existing Chemicals	No mandatory review	EPA must evaluate existing substances	Matches REACH's Substance Evaluation
New Chemicals	Limited oversight	Must prove no "unreasonable risk" before approval	Similar to REACH's pre-market review
Testing Authority	Testing required rulemaking	EPA can mandate testing directly	Closer to REACH's data-on-demand model
Prioritisation	No risk-based sorting	High/low priority substances identified	Mirrors REACH's CoRAP system
CBI Protections	Broad, unverified claims allowed	Must justify and renew claims	Aligns with REACH's CBI rules
Public Access to Data	Limited publication	Risk decisions and data must be disclosed	Echoes REACH's public ECHA database

U.S. TSCA

The EU's REACH and the United States' Toxic Substances Control Act (TSCA) differ markedly in structure.

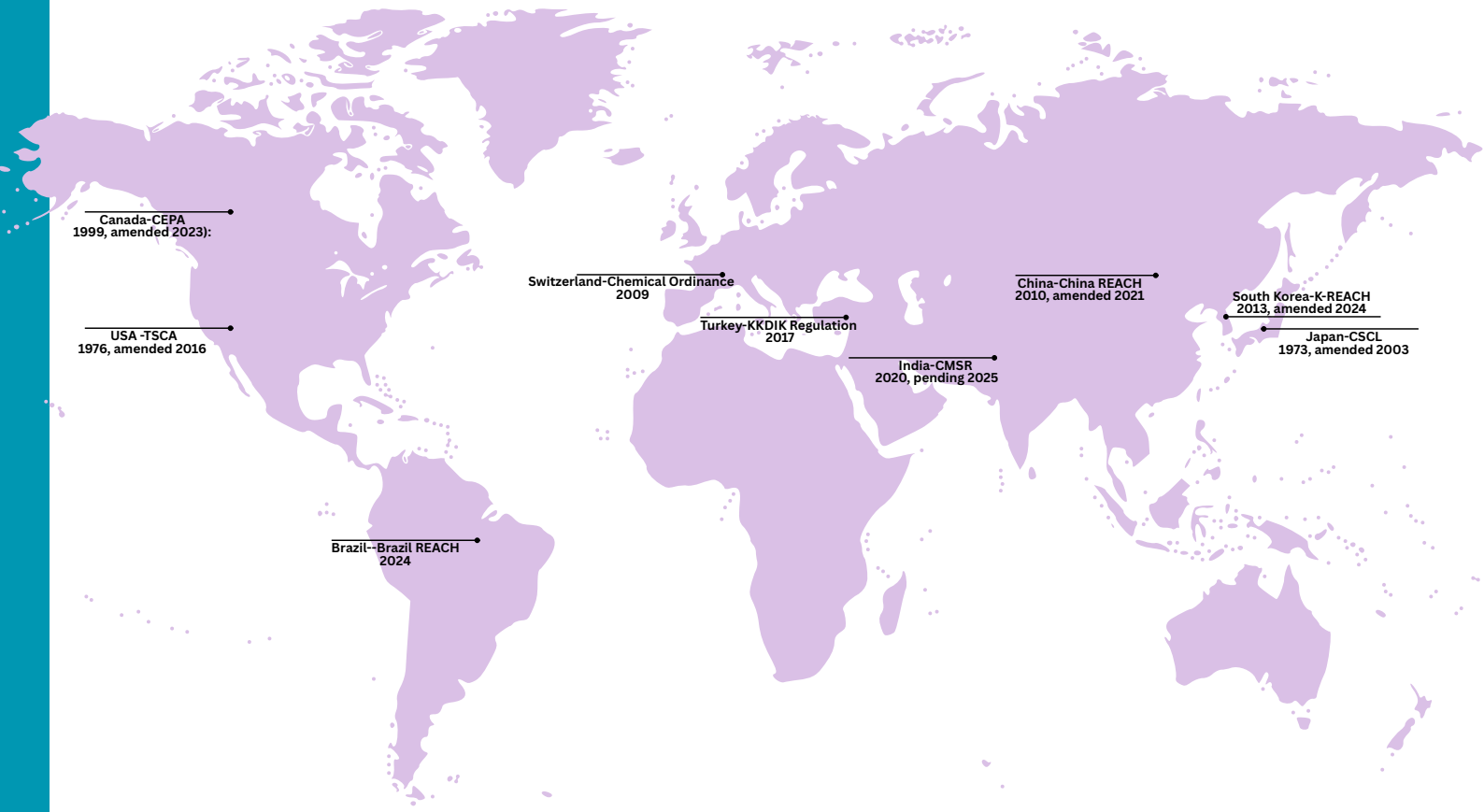
REACH places the burden of proof on industry to demonstrate substance safety before market entry. In contrast, TSCA traditionally allowed chemicals to enter the market with limited data, though the 2016 Frank R. Lautenberg Chemical Safety Act introduced significant reforms, granting the U.S. Environmental Protection Agency (EPA) greater authority to require testing and restrict chemicals.

For more information:
https://www.epa.gov/tsca-inventory

8.3 Harmonisation and Global Best Practices

The global influence of the REACH Regulation extends far beyond the European Union. It has served as a model for numerous jurisdictions seeking to modernize their chemical management systems while improving public health, environmental protection, and industrial transparency.[19] Although no universal framework for chemicals regulation exists, REACH has contributed significantly to the emergence of global regulatory convergence.

Several countries have adopted or adapted REACH-like frameworks, embedding key features such as pre-market registration, hazard-based classification, risk communication, and restrictions on hazardous substances.[20] Notable examples include Turkey's KKDIK, Korea's K-REACH, Japan's CSCL, and emerging legislation in India, China, and Brazil.[21] [22] These systems reflect REACH's influence but vary in enforcement capacity, scope, and institutional maturity.



Source: RohsGuide. "REACH Regulations Worldwide." RohsGuide.com.
Please note that Brazil's REACH regulation has been adopted

In parallel, international organizations such as the OECD[23] and UNEP[24] have similar goals as REACH—particularly in areas like data-sharing, testing standards, and the promotion of alternatives to animal testing. This has facilitated a more coherent global approach to chemical regulation, even in the absence of formal harmonization.

Despite its limitations, REACH remains the benchmark for regulatory best practice.[25] It demonstrates how a comprehensive and precautionary approach to chemical safety can drive institutional strengthening, market reform, and cross-border environmental governance.

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19. Young, "EU as a Global Regulator?"
20. Cha and Koo, "Who Embraces Technical Barriers to Trade?".
21. Asian Chemicals Forum, "REACH-like Chemical Regulations in Asia."
22. RohsGuide. "REACH Regulations Worldwide."
23. RohsGuide. "REACH Regulations Worldwide."
24. ECHA, "All News – ECHA."
25. UNEP, Global Chemicals Outlook II.

ANNEXURES

Annex A: Glossary of Key Terms

Term	Definition
REACH	An EU regulation (EC No 1907/2006) for the Registration, Evaluation, Authorisation and Restriction of Chemicals, aiming to protect human health and the environment.
ECHA	The European Chemicals Agency, responsible for the implementation of REACH. It evaluates dossiers, manages databases, and supports enforcement via national authorities.
SVHC	Substances of Very High Concern that may have serious effects on human health or the environment (e.g., carcinogens, PBTs, endocrine disruptors).
Annex XIV	Also known as the Authorization List. Substances listed here require prior authorization for use or placement on the market after the sunset date.
Annex XVII	The Restriction List, specifying substances subject to bans or limited use within the EU due to unacceptable risk levels.
Dossier	A structured submission to ECHA containing technical and safety data, typically compiled via IUCLID software for registration purposes.
IUCLID	International Uniform Chemical Information Database software used to prepare registration dossiers for submission to ECHA.
Chemical Safety Report (CSR)	A report required for substances ≥10 tonnes/year, detailing the chemical safety assessment (CSA) including exposure scenarios and risk characterization.
SIEF	Substance Information Exchange Forum, a temporary consortium where registrants share data, costs, and jointly prepare dossiers.
OR (Only Representative)	A legal entity in the EU appointed by a non-EU manufacturer to fulfill registration and compliance obligations on their behalf.
CoRAP	Community Rolling Action Plan, a 3-year plan identifying substances for substance evaluation by Member State Competent Authorities.
CLP Regulation	The Classification, Labelling and Packaging Regulation (EC No 1272/2008) aligns EU hazard communication with the Globally Harmonized System (GHS).
PBT/vPvB	Persistent, Bioaccumulative and Toxic / Very Persistent and Very Bioaccumulative substances that pose long-term environmental and health risks.
Annex XV Dossier	A dossier format used to justify a proposal for restriction or identification of SVHCs, submitted by ECHA or Member States.
RAC	Risk Assessment Committee, responsible for assessing human health and environmental risks of substances.
SEAC	Socio-Economic Analysis Committee, evaluates socio-economic impacts of proposed authorizations or restrictions.
MSC	Member State Committee, resolves disagreements among Member States on regulatory decisions, especially evaluations and SVHC listings.
PPORD	Product and Process Oriented Research and Development, a REACH provision allowing temporary exemption from full registration during R&D.
GHS	The Globally Harmonized System developed by the UN for standardized classification and labelling of chemicals worldwide.
DUIN	Downstream User Import Notification, a transitional measure under UK REACH to notify continued imports of previously EU-registered substances.
CBI	Confidential Business Information, sensitive data protected under REACH to avoid harm to a company's commercial interests.

Annex B: Summary of REACH Annexures

Annex	Focus	Description
I	General Provisions for CSA	Outlines the structure and content of a Chemical Safety Report (CSR) and how to conduct a CSA.
II	Guide for SDS	Provides formatting and content rules for **Safety Data Sheets (SDS)**.
III	Criteria for Substances Subject to Registration	Lists criteria to identify substances that may pose risks and require registration.
IV	Exemptions from Registration — Low-Risk Substances	Lists natural and low-hazard substances exempted from registration (e.g., glucose, cellulose).
V	Exemptions from Registration — Based on Process or Use	Lists process-specific exemptions, such as non-isolated intermediates and waste.
VI	Information Requirements for Registration	Defines standard information requirements based on substance tonnage bands.
VII	Standard Testing Requirements (1–10 tonnes/year)	Minimum data sets required for low-volume substances.
VIII	Standard Testing Requirements (10–100 tonnes/year)	Expanded testing requirements for medium-volume substances.
IX	Standard Testing Requirements (100–1,000 tonnes/year)	Includes long-term toxicity and degradation studies.
X	Standard Testing Requirements (>1,000 tonnes/year)	Highest-level data requirements, including multigeneration and chronic studies.
XI	Rules for Adapting Standard Testing Requirements	Allows use of QSARs, grouping, weight-of-evidence, or waiving of tests under strict criteria.
XII	(Repealed)	Formerly covered R&D exemptions; now integrated into other sections.
XIII	Criteria for PBT and vPvB Substances	Defines Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB).
XIV	Authorisation List	Substances subject to prior authorisation for use or market placement.
XV	Dossier Format for SVHCs and Restrictions	Format for proposing a substance as an SVHC or submitting a restriction proposal.
XVI	Socio-Economic Analysis for Authorisation	Outlines the methodology for socio-economic justifications in applications for authorisation.
XVII	Restrictions List	Substances and uses that are restricted or banned in the EU

Annex C: List of Relevant Regulations and Resources

Primary EU Legislation

Document	Citation	Purpose
REACH Regulation	Regulation (EC) No 1907/2006	Establishes the EU framework for registration, evaluation, authorisation, and restriction of chemicals.
CLP Regulation	Regulation (EC) No 1272/2008	Aligns EU classification, labelling and packaging with the UN's GHS.
REACH Fee Regulation	Regulation (EC) No 340/2008 (as amended)	Sets out fees and charges payable to ECHA for REACH services.
Regulation on Public Access to Documents	Regulation (EC) No 1049/2001	Governs access to documents held by EU institutions, including ECHA.

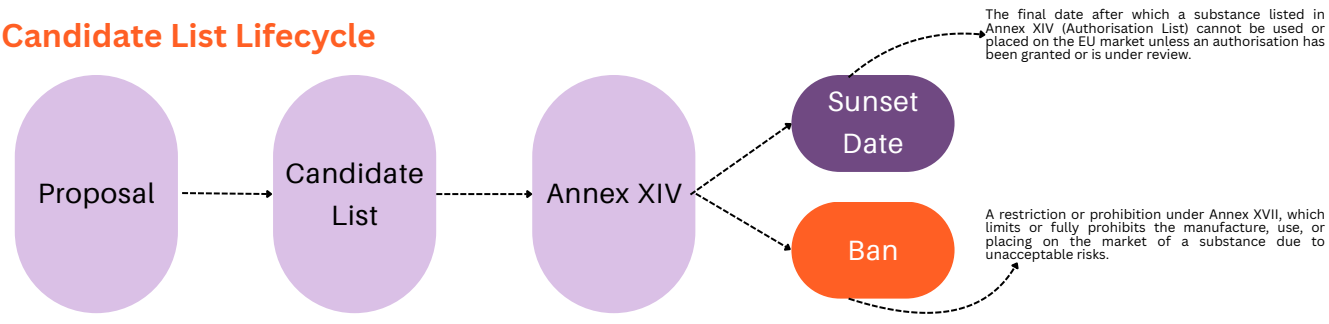
ECHA and Committee Guidance

Document	Issuing Body	Purpose
Guidance for Registration	ECHA	Explains how to prepare and submit REACH dossiers.
Guidance on Chemical Safety Reports	ECHA	Provides structure and content for CSRs, including exposure scenarios.
Guidance on the Application of the CLP Criteria	ECHA	Clarifies classification rules under CLP and GHS.
Rules of Procedure for RAC, SEAC, MSC, and Forum	ECHA	Defines operating rules and voting procedures of REACH committees.

Tonnage Threshold Summary Table

Tonnage Band (per year)	Annex Required	Testing Obligation
1–10 tonnes	VII	Basic physicochemical, toxicity, eco-toxicity
10–100 tonnes	VIII	Extended short-term studies
100–1,000 tonnes	IX	Long-term aquatic toxicity, degradation
>1,000 tonnes	X	Multigeneration toxicity, chronic exposure

Candidate List Lifecycle

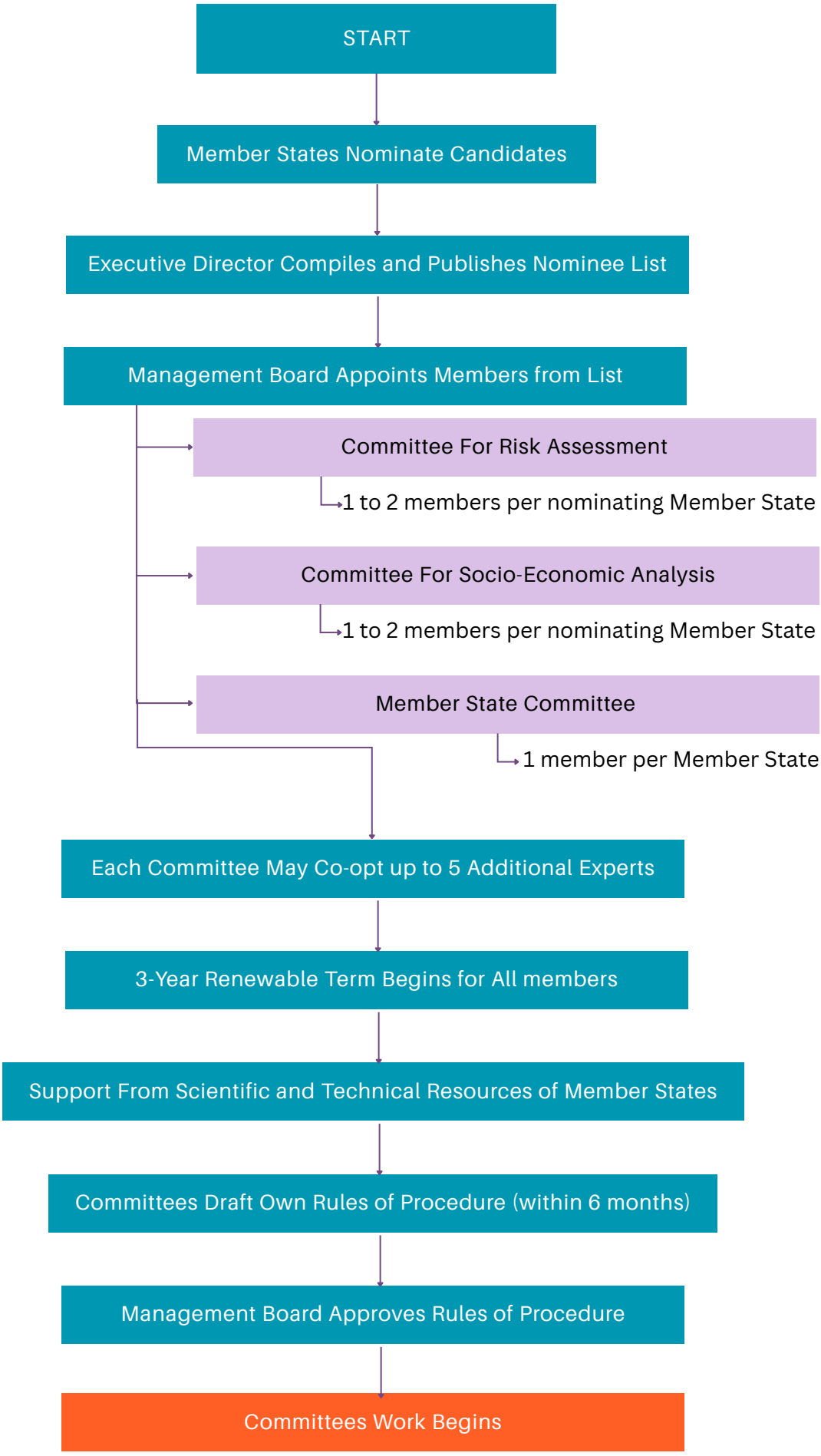


Annex D: Summary Tables

Safety Data Sheet (SDS) Content Template

Functional Group	Section	Description
Basic Product & Regulatory Info	Section 1	Identification of the substance/mixture and the supplier
	Section 2	Hazards identification (classification, labelling, risks)
	Section 3	Composition/information on ingredients
	Section 15	Regulatory information (EU/local legislation, restrictions)
	Section 16	Other information (abbreviations, references, revision history)
Emergency Response & Risk Mgmt	Section 4	First-aid measures
	Section 5	Firefighting measures
	Section 6	Accidental release measures
Handling & Exposure Control	Section 7	Handling and storage
	Section 8	Exposure controls/personal protection
Physical, Chemical & Stability	Section 9	Physical and chemical properties
	Section 10	Stability and reactivity
Toxicological & Environmental Info	Section 11	Toxicological information
	Section 12	Ecological information
Transport, Disposal & Compliance	Section 13	Disposal considerations
	Section 14	Transport information

Establishment of the Committees:



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