GoCompliance

Compliance for the Cloud

eBook

REACH

PRODUCT COMPLIANCE

Your Essential Guide to Managing Chemical Safety, Meeting EU Regulations, and Protecting Global Market Access.

INTRODUCTION

Navigating chemical regulations across international markets requires more than basic awareness. It demands a high level of precision, complete transparency throughout the supply chain, and a strategic approach to long-term compliance.

The European Union's REACH Regulation, which stands for Registration, Evaluation, Authorization, and Restriction of Chemicals, is one of the most comprehensive and influential chemical safety frameworks in existence. It applies not only to manufacturers and importers but also to distributors, assemblers, and downstream users who place products on the European market.

Unlike simpler regulatory regimes, REACH requires businesses to take full responsibility for understanding the substances used in their products and communicating that information both upstream and downstream. This includes obligations such as substance registration, hazard assessment, communication of safe use, and the provision of data to customers and authorities through Safety Data Sheets and SCIP notifications.

CONTENTS

CHAPTER 1:

SCOPE

Since REACH doesn't just apply to chemicals used as products on their own, but also to the substances and materials used in other products it is quite extensive in scope. These other products, referred to as "articles" in the regulation, include cleaning products, electrical appliances and components, vehicles, furniture, and other household items. The regulation applies to the majority of companies established inside the EU region, who either manufacture or import substances in quantities equal to or greater than one ton per year per company.

These companies fall into the following categories:

- **Manufacturers:** Businesses that produce chemicals, either for their use or to sell to others (including exporters).
- **Importers:** Businesses who purchase goods from outside the EU/EEA region. These goods can be chemical raw materials, semi-finished goods, or even finished goods which are composed of chemical materials or substances.
- **Downstream Users:** Other users who use chemicals in their industrial and professional activities. Many times these companies often don't realize which chemicals they are using and thus must regularly check their obligations.

NOTE: Although REACH does not apply directly to companies established outside the EU, these companies still bear indirect responsibility. They must ensure compliance by either collaborating with EU-based importers or appointing an Only Representative within the EU who assumes the legal obligations under REACH.

CHAPTER 2

IMPLEMENTATION

The REACH regulation consists of four main processes: Registration, Evaluation, Authorization & Restriction.

REGISTRATION

EU manufacturers and importers are legally required to register with the ECHA using a registration dossier, for any chemical substance they market or produce in quantities greater than or equal to 1 tonne per year. Companies are also mandated to collect information to identify and report all hazards and risks associated with these substances and declare how they intend to manage them.

PREREQUISITE: SUBSTANCE IDENTIFICATION

Before registration, it is essential to first accurately identify substances. Substances are defined as chemical elements which are often identified by a name (e.g Lead), a number (e.g. CAS Number 7439-92-1), and a composition (e.g. 92% Lead and 8% Oxygen). Substance identification is crucial for the “One substance, one registration” principle under which companies producing or importing the same substance must work together and submit a single registration.

It is necessary for companies to fully and completely share data in a fair, transparent, and non-discriminatory way. Before submission of a substance, companies must also first inquire from ECHA if there is already a pre-existing registration for it (in which case, the substance would not be registered again). Accurate identification is also important for any substance-related exemptions, evaluations, and risk assessments.

APPLICABILITY

Registration applies to:

- Substances used on their own
- Substances used in mixtures
- Specific substances used in articles

KEY DEFINITIONS

The ECHA defines substances, articles, and mixtures in the following way. For further details refer to the Guidance on Registration provided on the ECHA website. Substances such as medicines or radioactive materials which are already subject to other legislation may be partially or fully exempted from REACH.

SUBSTANCES refer to chemical elements and their compounds. This includes both substances obtained by a manufacturing process (e.g. methanol) and substances in their natural state (e.g. essential oils). It also includes any additive necessary to preserve the substances' stability.

ARTICLES are objects which during production are given a special shape, surface or design which determines their function to a greater degree than does their chemical composition (e.g. manufactured goods such as textiles, electronic chips and toys).

A **MIXTURE** refers to a blend of substances, integrated in measured portions, and which is not the result of a chemical reaction. Typical examples include paints, varnishes and inks. The REACH Regulation refers to alloys as 'special mixtures' and thus, even if they are not subject to registration, the alloying elements (e.g. metals) must be registered.

WHO NEEDS TO REGISTER

Registration is needed from the following:

- **EU manufacturers/importers** using substances on their own or in a mixture
- **EU producers/importers** of articles meeting the criteria explained in the Guidance on requirements for substances in articles

An EU-based "Only representative" is appointed by a non-EU-based manufacturer, formulator, or article producer to fulfill the importers' registration obligations. It should be remembered that the burden of proof to confirm compliance lies with the EU companies.

The process of inquiring from the ECHA and registering substances must be done before they're manufactured or imported. Companies must also ensure that the information contained in their registration dossiers is correct at the time of submission and that any subsequent changes are timely reported.

It should be remembered that the burden of proof to confirm compliance lies with the EU companies. The process of inquiring from the ECHA and registering substances must be done before they're manufactured or imported. Companies must also ensure that the information contained in their registration dossiers is correct at the time of submission and that any subsequent changes are timely reported.

EVALUATION

After companies submit registrations, the ECHA and the Member States check whether they comply with REACH requirements. The Evaluation process can be defined by two types of evaluations which focus on a total of three different areas:

DOSSIER EVALUATION

ECHA confirms that registration dossiers contain the necessary information on substances needed by the legislation. Under this, the agency:

- Examines the quality of testing protocols
- Confirms that the submitted registration dossiers comply with the REACH requirements

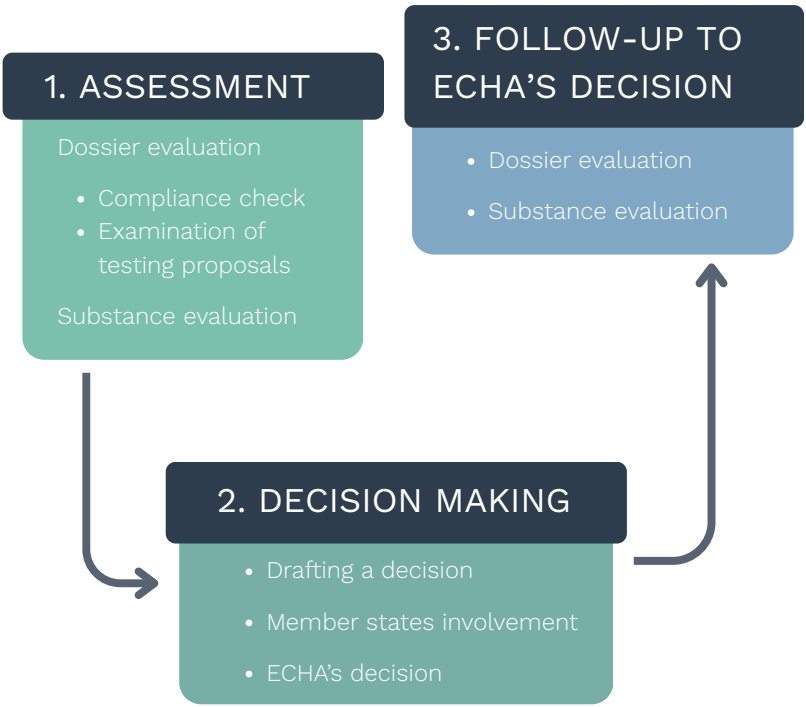
SUBSTANCE EVALUATION

Member states assess substances after they have identified specific concerns. They:

- Evaluate substances to clarify that they are not a threat to human health or the environment.

EVALUATION PROCESS

The evaluation process consists of three phases:



In case the given information is not sufficient for substance evaluation, the Member States may require companies to submit or generate additional details. The ECHA website also lists recommendations for registrants to improve the quality and relevance of their submissions.[5.]

[5] The Recommendations to registrants can be assessed here.

As mentioned earlier, the regulation calls for companies to progressively substitute their most dangerous substances, referred to as substances of very high concern or SVHCs, with safer alternatives. The Authorization process aims to:

- Ensure proper management and control of the risks and hazards associated with SVHCs) throughout their lifespan.

- Facilitate the systematic replacement of SVHCs with technically and economically feasible alternatives. These substitutes can be less dangerous substances, new technologies, and processes.

SUBSTANCES OF VERY HIGH CONCERN

The process of authorization commences when a Member State or ECHA, at the behest of the Commission, proposes to identify a substance as an SVHC. These substances may be:

- Substances that fall under the umbrella of being classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) category 1A or 1B per the CLP Regulation.

- Substances that are persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII. Substances on a case-by-case basis, causing an equivalent level of concern as CMR or PBT/vPvB substances.

CANDIDATE LIST

The SVHC identification process includes a 45-day consultation. Once identified the SVHC is included in the Candidate List which brings immediate obligations for the suppliers of the substance, such as:

- Supplying a safety data sheet
- Communicating on safe use
- Responding to consumer requests within 45 days
- Notifying ECHA if the article they produce contains an SVHC in quantities above one tonne per producer/importer per year and if the substance is present in those articles above a concentration of 0.1% (w/w)

AUTHORIZATION LIST

Substances in the Candidate List are regularly assessed by ECHA based on priority on whether they should be included in the authorization list (Annex XIV of the REACH Regulation). Prioritization is done based on information on the innate properties, wide range of use, or high volumes that fall within the sphere of the authorization requirement. A 3-month long consultation period is included as part of the process.

The draft recommendation includes the following information as well as other things:

- Sunset date: The date set after which the substance is prohibited from being marketed and used unless authorization is granted or the use is exempted from authorization.

- Latest application date: The deadline by which applications must be received if companies want to continue marketing or using a substance after its sunset date.

- Review periods: Periods to review certain uses if any.

- Uses exempted: Those which are exempted from the authorization requirement, if any.

ECHA's recommendations are submitted to the European Commission, which makes the final call on the substances included in the authorization list. These recommendations include exemptions from the authorization requirements. ECHA may propose some general as well as substance and use-specific exemptions. The latter is for cases where there is already a pre-existing EU legislation that sets the minimum requirements for the proper mitigation of risks needed to protect human health or the environment.

APPLICATIONS FOR AUTHORIZATION

Manufacturers, importers, and downstream users are allowed by REACH to submit applications to extend the usage and marketability of a substance beyond the sunset date. The Commission, after receiving opinions from the ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC), makes the final decision on whether authorizations are granted or refused.

ECHA strongly emphasizes supply-chain communication in the authorization process, as the coverage of authorization can extend beyond the applicant in the supply chain.

Thus manufacturers and downstream users of substances must from the very beginning share information and discuss the most efficient form of coordination. GoCompliance offers effective supply chain management which reduces both time and costs involved in maintaining working relationships with third parties (See Chapter 4).

Article 60 of the REACH Regulation defines the criteria for granting authorization under two main routes:

- Adequate control route: If the risk to human health and the environment from the usage of the substance arising from the intrinsic properties specified in the authorization list is adequately controlled.
- Socio-economic route: If it is shown that the socio-economic benefits from the usage of the substance outweigh the risk to human health and the environment and there are no suitable alternative substances or technologies.

ECHA urges potential applicants to communicate their intention to apply for authorization as early as possible. Applications must be submitted in the format of an IUCLID dossier attached with the following assessment reports and supporting documents:

- Chemical safety report: A chemical safety assessment of the substance which includes the plan to adequately control or mitigate the risk arising from its usage.
- Analysis of alternatives: An analysis showing whether there are any suitable alternative substances or technologies.
- Socio-economic analysis: Socioeconomic arguments in favor of the application.

For threshold substances where adequate control is shown and where suitable substitutes are available, the application must include:

- Substitution plan: A plan demonstrating the applicant's commitment to undertake the necessary actions needed to replace the SVHC with suitable substitutes for the uses applied for within a specified timeframe.

All necessary formats for application are provided by ECHA. Details on the supply-chain coverage and the authorization procedure can also be viewed on the ECHA website.

APPLICATIONS FOR AUTHORIZATION

The Authorization process can thus be defined in a three-phased process as shown below:

1. SUBSTANCES OF VERY HIGH CONCERN

- Registry of SVHC intentions until outcome
- Preparing the SVHC dossier
- Consultation
- Adding substances to the candidate list

2. RECOMMENDATION FOR INCLUSION IN THE AUTHORIZATION LIST

- Prioritization
- Draft recommendation
- Consultation
- MSC opinion
- Recommendation and inclusion in the Authorization list

3. APPLICATION FOR AUTHORIZATION

- Application for authorization
- Consultation
- RAC and SEAC opinions
- Implementation
- Review report, if the company needs to continue using the substance after the end of the review period

RESTRICTION

The Member States or the ECHA can initiate the Restriction procedure when they suspect a certain substance poses an unacceptable risk to human health or the environment. ECHA can also set restrictions on articles containing substances that are on the Authorization List (Annex XIV). The intention to prepare a restriction proposal is made public in the registry of intentions in advance of the preparation as an early warning.

Restrictions usually limit or ban the production, placement on the market, or usage of a substance. Sometimes, a restriction may impose specific conditions such as technical measures or labeling requirements.

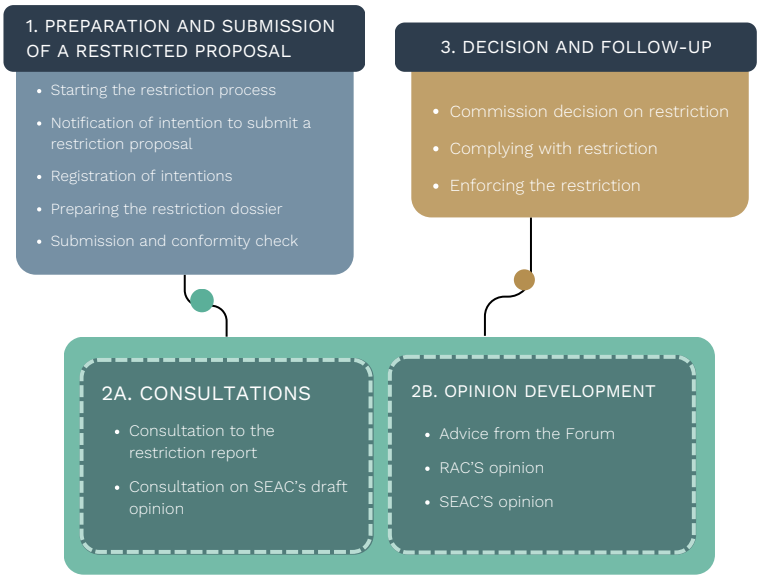
A restriction may be applied to any substance on its own, in a mixture, or in an article. The substance may even not need to be registered under REACH (such as substances manufactured or imported below one tonne per year or certain polymers).

While REACH restrictions generally do not apply to substances used exclusively in cosmetics for human health risks, they may still apply if the substance poses environmental risks. This distinction should be clearly understood when assessing exemption eligibility.

Once the restriction has been adopted, the industry is mandated to comply. This includes all manufacturers, importers, distributors, downstream users, and retailers. Enforcement is the national responsibility of member states. Restrictions on substances, mixtures, and/or articles are set out in Annex XVII to REACH.

RESTRICTION

The Restriction process involves the following phases:



CHAPTER 3

CANDIDATE LIST SUBSTANCES IN ARTICLES

REACH defines an article as an object that during production is given a special shape, surface, or design that determines its function to a greater degree than its chemical composition. According to REACH, articles include clothing, flooring, furniture, jewelry, newspapers, and plastic packaging.

Identifying a substance as a Substance of Very High Concern (SVHC) and its inclusion in the Candidate List can impose legal obligations on the importers, producers, and suppliers of an article that contains it. Producers and importers of articles can obtain relevant information on the substances present in them and their concentrations from members up in their supply chain, e.g. article suppliers outside the EU and suppliers of substances and mixtures.

Under REACH, there are two main obligations for articles containing Candidate List substances:

Notification of substances in articles: Producers and importers of an article must submit a notification to ECHA, no later than six months after the inclusion of the substance in the Candidate List, if the following conditions are met:

- The substance is present in their relevant articles above a concentration of 0.1% weight by weight.
- The substance is present in these relevant articles in quantities totaling over one tonne per year.

EXEMPTIONS

There are two instances when a notification is not needed:

- The producer or importer of an article can exclude the exposure of humans and the environment to the substance during normal or reasonably foreseeable conditions of use of the article, including its disposal. In such cases, the producers and importers must give appropriate instructions to the article recipient.

- The substance has already been registered by a manufacturer or importer in the EU for that use.

COMMUNICATION IN THE SUPPLY CHAIN

Immediately after the inclusion of a substance in the Candidate List, suppliers of articles that contain this substance in a concentration above 0.1% (weight by weight) must provide enough information to allow the safe use of these articles to the recipients who use them. In these cases, recipients include industrial or professional users and distributors, but not consumers. At the very least, the name of the substance must be communicated. Consumers also have the option to request similar information, and the supplier must provide it within 45 days, free of charge. Chapter 4 provides details on how gocompliance can help you with effective communication in the supply chain.

Details on the requirements on substances in articles can be found on the ECHA website.

CHAPTER 4

ENFORCEMENT

Enforcement of the REACH Regulations is a national obligation and thus must be done by the EU Member States, Norway, Iceland, and Liechtenstein. Since ECHA is a Community-level institution, it has no enforcement responsibilities. However, it does host the Forum for Exchange for Information on Enforcement where representatives of national enforcement authorities, coordinate together to work on the enforcement of REACH and other regulations.

Non-Compliance with the REACH Regulation can have serious legal ramifications. Article 126 of REACH refers to the duty of the Member States to impose “penalties” for infringement. In the context of REACH, the term “penalty” is equivalent to “sanctions” characterized by their punitive or repressive characteristics.

The type of penalty varies among the Member States. In general, the states have progressively included fines in their penalty systems. Other penalties include injunctions (including market withdrawal), prison sentences, and name-and-shame methods where non-compliance is made public. Often initial warnings and formal notices of infringement precede penalties. Further details on penalties can be viewed on the ECHA website.

CHAPTER 5

GOCOMPLIANCE & EFFECTIVE COMMUNICATION IN SUPPLY CHAIN

Effective communication across the entire supply chain is a key element at all stages in the REACH process and is crucial to ensure that all relevant information is duly exchanged. From the Registration phase to the Authorization stage, it is essential that different parties effectively communicate with each other to ensure successful compliance. Different actors in the supply chain can have several roles, depending on which they can have different obligations. These actors range from manufacturers, importers, and only representatives to distributors and downstream users and may need different tools and information to aid their processes.

When downstream users provide suppliers with information regarding their uses and conditions, the registrants can include this while formulating the exposure scenarios in their chemical safety assessments. Consequently, suppliers and manufacturers can pass down crucial information to downstream users. This can include data on the chemical composition of their products, mass composition, and advice on safe use.

GOCOMPLIANCE AT WORK

Being the only solution that sits on Oracle Cloud and is purpose-built and pre-integrated with Oracle PLM Cloud, gocompliance is dedicated to assisting the collection and tracking of material information necessary to inspect product compliance against more than 127 regulations, including REACH.

It is pre-loaded with over 2600 substances and offers multiple roll-up engines, thus enabling businesses to assess compliance with health & environmental regulations in an easy and systemized manner while keeping their team and suppliers in the loop throughout.

Through gocompliance, compliance managers and suppliers can effectively communicate with each other in a timely and cost-effective manner. They can identify regulated substances used in products and check if they comply with desired regulations including but not limited to REACH. gocompliance can play a key role in helping companies gather relevant data from suppliers, check for and manage SVHCs and stay up-to-date with authorization deadlines and updates to the regulation process. It can also exchange data to external systems such as Agile PLM or Oracle PLM Cloud.

Rquesting compliance in gocompliance consists of 4 main steps:

1 KEEPING TRACK OF REGULATORY INFORMATION

Select the item you would like to get the information on.

2 FILL DECLARATION (SUPPLIER)

To fill the declaration import a pre-existing declaration or manually enter the required details. Upload a supporting document if needed and submit the declaration so it can reach the compliance manager.

3 DECLARATION APPROVAL (COMPLIANCE MANAGER)

Once a declaration is received, the compliance manager can edit, accept or reject the declaration. If the declaration is rejected, the supplier is notified and can review the declaration.

4 REQUEST COMPLIANCE (COMPLIANCE MANAGER)

Choose the compliance option, request declaration by providing the required details, and then send the declaration request to the supplier.