EU REACH Reporting using DXC Compliance Solution

Monika E. Kotkowska

Ashfaquzzaman Syed

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In Navigating Environmental Compliance and Market Regulations

Discover the game changing possibilities that come with embracing sustainability via the REACH Regulation. By doing so, your business can move towards an environmentally friendly future, all while keeping up with the constantly changing regulatory environment.

Table of contents

Executive Summary 4

REACH Registration: Complying with EU Chemical Regulations..... 6

Who Needs to Register? 6

Registration Timelines:.....7

REACH Evolution: Enhancing Chemical Safety 8

REACH Authorization: Safeguarding Health and Environment from Hazardous Substances 9

REACH identifies SVHCs based on the following criteria: 9

Authorization Process: 9

REACH Restrictions: Ensuring Compliance.....10

REACH Annex XIV and SVHC Authorization.....10

REACH Annex XVII: Limitations and Restrictions.....10

Prohibitions Imposed by REACH Annex XVII 10

Understanding the Scope and Exceptions of REACH Compliance.....11

Exemptions from Specific REACH Titles.....11

Additional Exclusions from REACH Compliance.....11

Obligations of Manufacturers and Importers 11

Extent of SVHC Reporting 12

Packaging Implications 12

Mandatory Nature of REACH Compliance.....12

Managing Compliance through Solution 13

CDX: Streamlining Regulatory Compliance 13

IMDS: Transforming Automotive Material Compliance.....13

Key Definitions for Compliance 14

References.....15

Executive Summary

The European Union (EU) recognizes that chemical substances are widely found in products, across various industries and acknowledges their potential impact on human health and the environment. To address this concern the EU implemented the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) regulation on January 1 2007. This extensive regulation spans 849 pages. It applies to manufacturers, importers and downstream users of substances within the EU. Its primary goal is to ensure that products do not have any effects, on health or the environment.

Introducing the REACH regulation, initiated by the European Union in December 2006 and enforced from January 1, 2007. REACH ensures that manufacturers and suppliers carefully examine the risks of chemicals in their products to protect people's health and the environment.

REACH covers substances both in their pure form, as well as in preparations (mixtures or solutions) and articles (finished products). The European Chemical Agency (ECHA) oversees the administration of REACH and regularly publishes progress reports on the registration and evaluation of chemical substances. In 2018, the regulation was amended to include specific information requirements for nanomaterials.

The key objectives of REACH are to safeguard human health and the environment, enhance transparency in identifying harmful chemicals, promote the competitiveness of the EU chemical industry, comply with international obligations, and encourage the use of non-animal testing for data sharing.

REACH regulation encourages responsible practices, requiring companies to take specific actions to reduce any harmful effects caused by these chemicals.

While this document focuses on EU REACH, it's worth noting that other jurisdictions such as Turkey, Iceland, Japan, and Taiwan have their versions of REACH, with both similarities and differences. Nevertheless, the EU's REACH regulation remains a significant step towards ensuring chemical safety and sustainable development in the region.

Step into the future of sustainability with CDX users as we wholeheartedly embrace the REACH movement. Together, we're building a safer, greener world for everyone.

This whitepaper provides an in-depth understanding of the scope of REACH, its coverage of substances in various forms, and its objectives aimed at safeguarding human health, the environment, and fostering innovation in the EU chemical industry. Furthermore, the paper emphasizes the importance of promoting non-animal testing and maintaining compliance with international obligations for creating a harmonious global chemical landscape.

REACH: Where Chemistry Meets Responsibility

Discover the fascinating world of REACH, a powerful regulation that has a significant impact on substances within the European Union. From the tiniest molecules to complex mixtures and even the coolest finished products, REACH covers it all!

The REACH regulation applies to substances manufactured or imported into the European Union (EU) in quantities equal to or exceeding 1 ton per year (tpa). It covers substances in their individual form, as part of a preparation (e.g., mixtures or solutions like ink or detergents), or as constituents of an article (objects with distinctive shapes, surfaces, or designs that determine their function, such as cars, clothes, or toys). Once classified as an article under REACH, it maintains that classification throughout its lifecycle.

Transparency is prioritized as REACH aims to identify the chemicals encouraging the use of safer alternatives.

REACH diligently focuses on addressing gaps in data concerning chemical properties and usage ensuring it aligns with the World Trade Organization (WTO) and global initiatives.

Administered by the European Chemical Agency (ECHA), REACH requires reports on the progress of registration and evaluation from registrants. These reports include recommendations to potential manufacturers and importers to continuously enhance the quality of information provided.

In April 2018, REACH was amended to include specific information requirements for nanomaterials.

The objectives of REACH, which must be balanced within the framework of sustainable development, are as follows:

Protecting Human Health and the Environment: The regulation empowers manufacturers, suppliers, and importers to identify and manage the properties of chemical substances that pose risks, ensuring the safety of human health and the environment.

Enhancing Transparency: REACH aims to identify and address the most harmful chemicals by encouraging the use of safer alternatives. Nearly all substances fall under this regulation unless explicitly exempted.

Boosting Competitiveness in the EU Chemical Industry: The regulation fosters innovation, research, and development to promote safer substances in industries involved in chemical and materials development, thereby strengthening the EU chemicals industry's competitiveness.

Meeting EU International Obligations under the World Trade Organization (WTO): REACH addresses data gaps related to properties and usage of chemical substances in all types of products manufactured or imported into the EU while maintaining alignment with international efforts.

Promoting Non-Animal Testing: Companies are required to share data to avoid unnecessary testing on vertebrate animals. Before conducting proposed tests, they must obtain approval from ECHA, and such tests can only be performed when all other relevant and available data sources have been thoroughly reviewed.

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REACH Registration: Complying with EU Chemical Regulations

Registration is a crucial requirement for REACH compliance. Manufacturers must gather information on the chemical substances they produce or import into the European Union and submit it to the European Chemicals Agency (ECHA) through a Registration Dossier. Polymers and non-isolated intermediates are exempt from this requirement

The Registration Dossier should contain details about how the chemical substance is used, including its physico-chemical, ecotoxicological, and toxicological properties, along with a hazard and risk assessment. The risk assessment should demonstrate how the use of these substances may impact human health and the environment and how these risks are controlled, ensuring the safety of downstream users:

Who Needs to Register?

Registration is mandatory for the following entities:

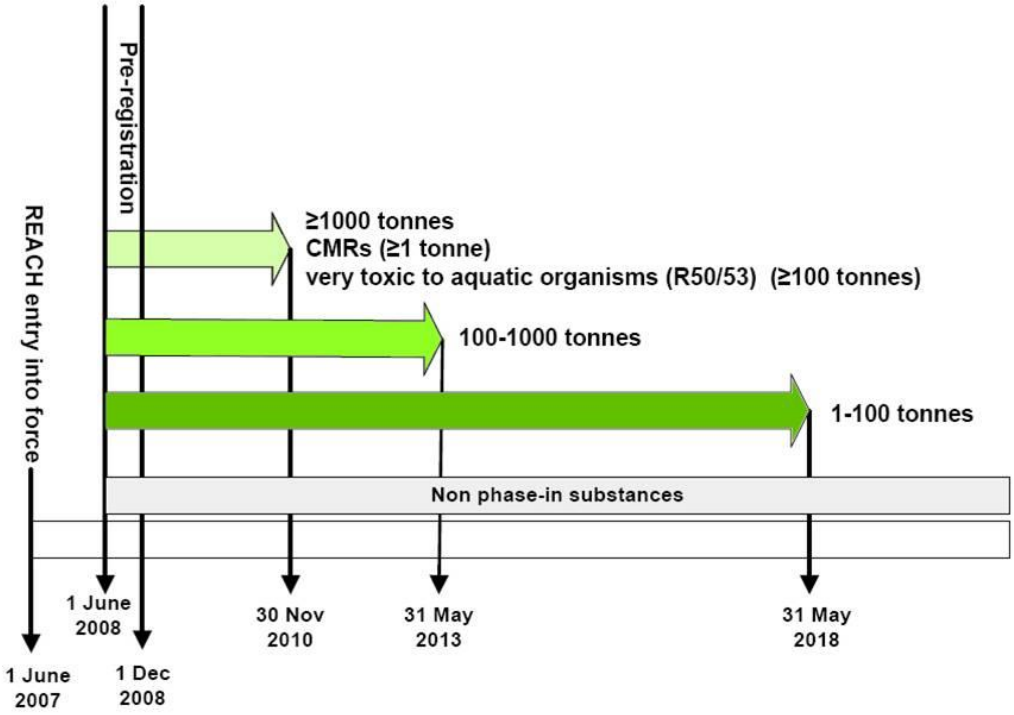
- **European Union Manufacturers:** Natural or legal entities within the EU who make or assemble an article.
- **Only Representatives:** These representatives are established within the EU and appointed by manufacturers, formulators, or article producers residing outside the EU. Only Representatives fulfil the registration obligations of importers.
- **Importers:** Entities established in the EU, responsible for importing substances. Legal entities should complete the registration. Import responsibility depends on various factors, such as ordering, payment, and handling customs formalities, but this may not be conclusive on its own.

The registration process is simplified through the **"one substance, one registration"** principle. If multiple manufacturers and importers import or produce the same chemical substance, they can jointly submit the registration, provided the properties based on analytical and/or spectral analysis are consistent to confirm identical substance use.

All standalone substances, substances in mixtures, and specific cases of substances in articles must be registered. However, certain chemical substances already regulated by other legislations, such as medicines or radioactive substances, are partially or completely exempt from REACH Registration.

Registration Timelines:

- 1 June 2007: REACH was launched.
- 1 June 2008: Pre-registration for existing (phase-in) substances began. Registration for new (non-phase-in) substances started.
- 30 November 2008: Pre-registration for 'phase-in' substances ended.
- 1 December 2008: Registration for existing substances (not pre-registered) started.
- 1 January 2009: List of pre-registered substances published, and Substance Information Exchange Forums (SIEFs) were formed.
- 1 December 2010 (Phase 1): By this date, pre-registered 'phase-in' substances with supply quantities at or above specific thresholds should have been registered.
- 1 June 2013 (Phase 2): Deadline for registering substances with quantities between 100 - 1000 tpa.
- 1 June 2018 (Phase 3): Companies manufacturing or importing substances in low volumes, between 1 - 100 tpa, should have registered by this deadline.



Source::http://www.cirsreach.com/REACH/REACH_Registration_Deadlines.html

All standalone substances, substances in mixtures, and specific cases of substances in articles must be registered. However, certain chemical substances already regulated by other legislations, such as medicines or radioactive substances, are partially or completely exempt from REACH Registration.

REACH Evolution: Enhancing Chemical Safety

The evaluation process plays a crucial role in ensuring the safety of chemical substances within the European Union (EU). It involves a comprehensive examination of the information provided by manufacturers and importers through the Registration process, with the aim of assessing potential risks to human health and the environment.

The evaluation process consists of several essential steps:

- **Compliance Checking:** The European Chemicals Agency (ECHA) meticulously checks and assesses the quality of the information submitted by registrants. This step ensures that the data provided meets the necessary standards for evaluation and helps maintain the integrity of the evaluation process.
- **Dossier Evaluation:** For substances registered at higher tonnage levels (≥100 tonnes per annum), registrants must submit proposals outlining any animal tests they believe are necessary, as specified in Annexes IX and X of the REACH regulation. ECHA then evaluates these testing proposals, aiming to prevent unnecessary animal testing and minimize associated costs while still ensuring thorough safety assessments.
- **Substance Evaluation:** Competent Authorities within the European Economic Area (EEA) member states conduct the evaluation of chemical substances. This evaluation process is a collaborative effort between the European Commission (EC) and the Competent Authorities. It involves a prioritization of substances based on their potential risk, followed by the determination of appropriate regulatory actions.

Possible Outcomes of Substance Evaluation:

The substance evaluation may lead to several different outcomes, depending on the findings:

- **No Significant Hazard**: If the evaluation reveals that the chemical substance does not pose significant risks to human health or the environment, it may be deemed safe for its intended uses.
- **Imposition of Restrictions:** In cases where potential risks are identified, the evaluation may result in the imposition of specific restrictions on the manufacturing, supply, or use of the substance. These measures aim to minimize exposure and mitigate any potential adverse effects.
- **Addition to the Priority List for Authorization:** Substances of particular concern may be added to the priority list for authorization. This list includes substances subject to strict control measures to ensure their safe handling and use.

Proposal to Change Classification and Labelling Requirements: If the current classification and labelling of the substance are deemed inadequate, the evaluation may lead to a proposal for appropriate changes. Accurate labelling is essential to communicate potential hazards and safe handling practices to users.

REACH Authorization: Safeguarding Health and Environment from Hazardous Substances

The REACH authorization process is instigated when either the European Chemicals Agency (ECHA) or a Member State proposes the identification of certain chemical substances or groups of substances as Substances of Very High Concern (SVHCs). These substances exhibit severe adverse effects on human health, including being carcinogenic, mutagenic, or toxic for reproduction.

REACH identifies SVHCs based on the following criteria:

- Carcinogenic, Mutagenic, or toxic for Reproduction (CMR) substances in Category 1A or 1B according to the Classification, Labelling, and Packaging (CLP) Regulation introduced by the EU in 2009.
- Substances that are Persistent, Bio-accumulative, and Toxic (PBT).
- Substances classified as Very Persistent and Very Bio-accumulative (vPvB) according to REACH Annex XIII.
- Substances causing concern equivalent to CMR or PBT/vPvB substances, determined on a case-by-case basis.

Authorization Process:

1. **Candidate List Inclusion**: Once identified, the substance is added to the Candidate List. This list serves to inform substance manufacturers, importers, and suppliers, urging them to take specific actions:
    a. **Provide a Safety Data Sheet (SDS)** containing classified substance details. SDS ensures safety information dissemination throughout the supply chain, aiding risk management by downstream users.
    b. **Communicate safe substance usage:** Suppliers must provide REACH SDS, physically or electronically, to customers before or during initial chemical delivery if the substance is a hazardous SVHC.
    c. **Offer Safe Use Instructions (SUI):** Suppliers must offer SUIs including SVHC utilization exposure scenarios and other essential information.
2. **Consumer Requests and Notification**:
    a. **Address consumer queries within 45 days:** According to REACH Article 33, manufacturers must promptly respond to consumer requests for SVHC information in products or packaging, where concentrations exceed 0.1%. This information provision is free and should occur within **Notify ECHA about SVHC-containing articles:** If articles hold SVHCs above 0.1% (w/w) at quantities exceeding 1 metric ton per producer/importer per year, notification to ECHA is obligatory.

This comprehensive process ensures the responsible handling of hazardous substances under REACH, promoting safety, transparency, and regulatory adherence across the supply chain.

Start your compliance journey, with CDX today. Ensure safety through understanding. Enhance your understanding of product knowledge to address REACH restrictions. Take the stride towards a future that is both safer and more compliant. Begin your path to achieving excellence, in REACH regulations !

REACH Restrictions: Ensuring Compliance

Chemical restrictions establish a structured process governing the introduction of hazardous chemical substances and products into the European Union (EU). These measures are designed to safeguard human health and the environment from the risks posed by such chemicals. In essence, restrictions function as a protective framework that mitigates potential dangers that might otherwise go unaddressed.

Chemical restrictions play a crucial role in upholding the safety of human health and the environment across the EU.

CDX software acts as your shield, helping you manage hazardous chemical substances and products as they traverse the supply chain. With CDX, you'll never overlook potential risks that could otherwise remain unnoticed.

CDX surpasses the constraints of CAS numbers. It brings about a transformation, in how you handle things by classifying substances into substance groups providing a comprehension of chemical components. This functionality guarantees that you can quickly recognize and handle substances even if they aren't obligated to be registered.

These limitations are applicable to a broad spectrum of substances, even those not mandatorily registered. When specific substances or preparations are identified as presenting significant risks necessitating collective action, restrictions can be imposed. These restrictions vary in nature, ranging from outright bans to constraints on providing certain articles to end consumers.

REACH Annex XIV and SVHC Authorization

An important reference is the REACH Annex XIV, updated as of January 10, 2018. This annex enumerates substances chosen from the REACH Substance of Very High Concern (SVHC) list that require authorization under the EU's REACH regulation. The substances listed, comprising SVHCs, are prohibited from being placed on the market or employed after designated "sunset dates." However, authorization can be granted for specific applications of these substances, or certain uses may be exempted from such authorization.

REACH Annex XVII: Limitations and Restrictions

The REACH Annex XVII regulation compiles an inventory of limitations pertaining to hazardous substances, mixtures, and articles in relation to their marketing and utilization within the EU market. This annex also includes a roster of substances subjected to restrictions with regards to their manufacture, import, usage, or presence in articles traded within the EU. This compilation is referred to as the REACH Restricted Substance List.

Prohibitions Imposed by REACH Annex XVII

Certain substances have been banned under the aegis of REACH Annex XVII. Notable among these are Polychlorinated Terphenyls (PCTs), asbestos fibers, pentachlorophenol and its salts and esters, as well as monomethyl-tetrachlorodiphenyl methane. Many of these substances are categorized as persistent organic pollutants (POPs).

Understanding the Scope and Exceptions of REACH Compliance

The ambit of REACH restrictions encompasses nearly all products that are manufactured within or imported into the European Union (EU) for general utilization. However, certain exemptions are integral to this REACH compliance framework.

Exemptions from Specific REACH Titles

REACH Titles II (Authorization), V (Downstream User), VI (Evaluation), and VII (Authorization) do not extend their applicability to the following categories:

- Medical products designed for human or veterinary purposes.
- Food products, including food flavorings and additives.
- Substances intended for Research & Development purposes.
- Specific substances that are explicitly listed in Annex IV and Annex V.
- Cosmetics, which are anticipated to fall under the purview of alternative regulatory measures.

Additional Exclusions from REACH Compliance

Beyond the mentioned, other instances exempted from REACH Compliance involve:

- Radioactive substances, projected to be subject to distinct compliance protocols.
- Substances earmarked for re-export or in transit, anticipated to adhere to separate compliance stipulations.
- Non-isolated intermediates, such as reactive chemicals that undergo further processing and cease to exist in their initial form after such processing.
- Waste materials, governed by the Waste Directive Framework (WDF). The WDF's anticipated release is slated for January 2020, with mandatory reporting starting from January 1, 2021.

Obligations of Manufacturers and Importers

- Manufacturers and importers located outside the EU bear direct legal responsibilities for reporting Substances of Very High Concern (SVHCs) identified by REACH if these substances are present in the products they offer within the EU market. Conversely, those manufacturers and importers that have established operations within the EU are directly accountable for adhering to REACH regulations and ensuring compliance.

Unlock a new era of efficiency and accuracy. Choose CDX software today and take control of your REACH compliance journey like never before. Say goodbye to confusion, and embrace a future where compliance is both simple and comprehensive. Your success is our priority!

Extent of SVHC Reporting

The obligation to report SVHC substances generally extends to product packaging, in addition to the products themselves. Packaging materials, like cardboard boxes, might encompass SVHCs such as boric acid or borate flame retardants. Notably, REACH Annex XVII restrictions often encompass packaging, particularly if it is intended for consumer use.

Packaging Implications

Packaging considerations encompass products in transit, such as pallets and banding materials. Prior to REACH implementation, lead was a commonly employed material to secure steel bands fastened to pallets. Consequently, unloading docks were often strewn with numerous small lead fragments resulting from broken clasps, with total lead quantities reaching tens or hundreds of kilos.

CDX takes the lead in the ever-evolving landscape of compliance. While REACH is at the core of what we do, we understand that borders blur in the realm of business. That's why CDX equips you to conquer compliance hurdles even in regions where EU operations aren't explicit. Compliance knows no boundaries with CDX by your side.

Mandatory Nature of REACH Compliance

The sphere of REACH compliance necessitates adherence for products either originated within or transported into the European Union (EU) and its member nations. While REACH is distinctive to the EU, it is noteworthy that various jurisdictions have introduced analogous regulations. Moreover, the proliferation of services has led to the sale of products in regions unintended for distribution. Consequently, businesses might find themselves obligated to adhere to REACH compliance even in the absence of explicit EU operations

Managing Compliance through Solution

Experience simplified compliance management with CDX and IMDS. Benefit from their comprehensive features, industry-standard material declarations, and robust data management enhance your product material compliance efforts with ease.

Simplified Compliance: Unlock the Power of CDX and IMDS

Experience streamlined compliance management with CDX and IMDS. CDS simplifies RoHS and REACH compliance through easy information exchange and accurate data management. IMDS revolutionizes material compliance in the automotive industry, ensuring REACH compliance and proper substance disposal.

CDX: Streamlining Regulatory Compliance

Ensure seamless REACH compliance and simplify regulatory material data management with Compliance Data Exchange (CDX) by DXC Technology. CDX offers a cloud-based Software-as-a-Service (SaaS) solution accessible through a web browser, eliminating the need for complex IT infrastructure. It facilitates the creation, search, extraction, evaluation, exchange, and retention of information required for REACH compliance. CDX includes data validation rules and curated substance lists to enhance accuracy and streamline data collection. Stay up-to-date with regulatory changes through CDX's regular updates from legal advisors, ensuring compliance with REACH and other regulations. Seamlessly integrate CDX with existing systems using the Web Services Interface (WSI) to automate data exchange and enhance product development and reporting workflows. CDX's reporting and analysis tools provide comprehensive insights for effective REACH compliance and other jurisdictional variations.

IMDS: Transforming Automotive Material Compliance.

Introduced in 2000, the International Material Data System (IMDS) revolutionized material compliance management in the automotive industry. Developed through collaboration between German Automotive OEMs, the chemicals and materials industries, and DXC Technology, IMDS is a secure cloud-based materials data management system. Accessible through a web browser, IMDS collects, maintains, analyzes, and archives material information throughout the automotive supply chain. IMDS not only facilitates compliance with REACH but also addresses recyclability, recoverability, and the disposal of substances of concern in automobiles. Its usage in the automotive industry enables easy compliance with REACH obligations and seamless communication of data without the need for additional tools or processes.

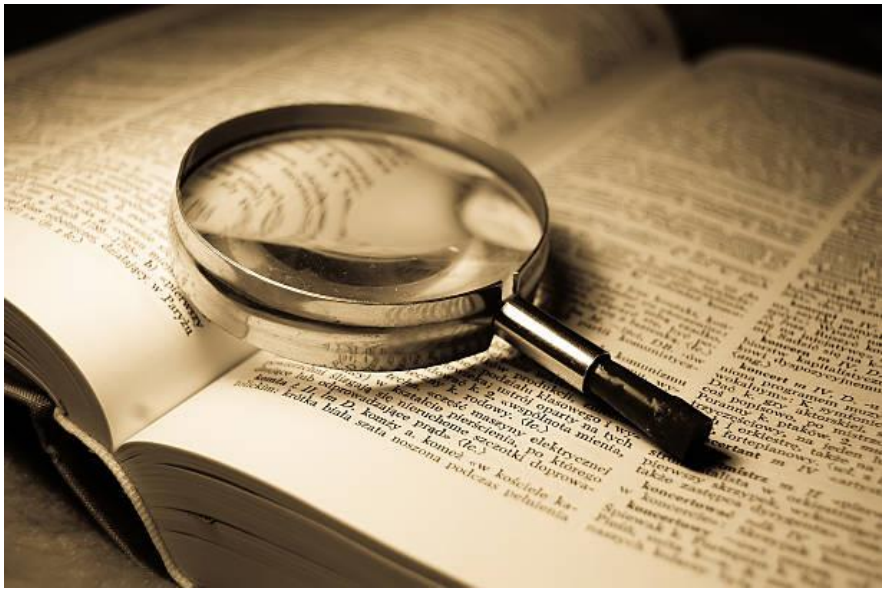
Key Definitions for Compliance

This summary provides an overview of important compliance definitions related to regulations governing electrical and electronic products.

Understanding these key compliance definitions is crucial for businesses operating within the electrical and electronic industry, ensuring adherence to regulations, and promoting sustainable practices.

- **Article:** An article is a completed product that can be sold. During its production, it acquires a distinct shape, surface, or design, which determines its function more than its chemical composition. Examples include cars, clothes, and toys. In the context of REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), the principle "Once an Article, Always an Article" (O5A) applies.
- **Chemical Safety Report (CSR):** For substances manufactured or imported in quantities of 10 tonnes or more, the Chemical Safety Report (CSR) documents the substance's hazards, classification, and whether it is Persistent, Bioaccumulative, and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB).
- **CHIP**: The Chemicals (Hazard Information and Packaging for Supply) Regulations of 2002**.**
- **Distributor:** A distributor is a legal or natural entity within the EU, including retailers, who stores and sells substances, either alone or within mixtures, to third parties (defined in Article 3(14)).
- **The European Economic Area**: Established through the EEA Agreement, the EEA extends the EU's single market to non-EU member countries.
- **Importer**: An importer is an entity introducing substances into the EU's customs territory (as defined in Article 3(10)).
- **Manufacturer**: A manufacturer is an entity within the EU that produces substances (as defined in Article 3(9)).
- **Manufacturing**: Manufacturing involves the production or extraction of substances in their natural state (defined in Article 3(8)). This is further detailed in Guidance on registration Version 3.0 – November 2016.
- **Only Representative:** An Only Representative is an EU-based entity appointed by a non-EU manufacturer, formulator, or producer to fulfil importer obligations (Article 8).
- to third parties, including imports (Article 3(12)).
- **Downstream user**: A downstream user, distinct from the manufacturer or importer, utilizes substances, alone or in mixtures, for industrial or professional purposes (Article 3(13)).
- **Producer of an article**: A producer of an article is an entity that manufactures or assembles an article within the EU (Article 3(4)).
- **Safe Use Instructions (SUI):** Suppliers are required to provide Safe Use Instructions, including exposure scenarios for Substances of Very High Concern (SVHCs), and other relevant information.
- **Substance**: A substance refers to a natural or manufactured chemical element and its compounds, including stability-preserving additives and impurities resulting from derivation processes. It excludes separable solvents that don't affect chemical stability or composition.

- **Substance Information Exchange Forum (SIEF):** The SIEF facilitates cooperation for REACH registration among co-registrants, often established for the phase-in scheme transitory period.
- **Supplier of a substance or a mixture**: This includes manufacturers, importers, downstream users, or distributors placing substances, alone or in mixtures, on the market.
- **Supply a Safety Data Sheet (SDS):** The Safety Data Sheet (SDS) documents information on classified chemical substances and preparations.
- **Use**: Use encompasses processing, formulation, consumption, storage, treatment, container filling, transfer, mixing, article production, or any other utilization (Article 324).



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