

# SA-G-205-01 Guidance - Material compliance - REACH management

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# 1. Overview

## 1.1. Purpose

This document describes how to fulfill the obligations of the REACH regulation, which concerns chemicals as such, in preparations and in articles.

## 1.2. 1.2 Scope

This Standard applies to all Hitachi PG units in all Hitachi PG legal entities, including joint ventures/ consortia/ working partnerships with management control.

# 2. Guidance

## 2.1. PG and you - roles and responsibilities

BU manager is responsible for reviewing the obligations from the REACH regulation on a regular basis. A review should also be made when there are relevant changes in the business, in environmental competence or in external requirements from authorities, owners, customers or other stakeholders. BU manager is responsible for communicating changes in the legal requirements to the management team.

The management team is responsible for ensuring that REACH obligations are met and ensuring that funds are allocated to this in the budget. REACH obligations should be taken into account when designing strategic plans for the business.

## 2.2. REACH regulation

The EU regulation on chemicals and their safe use, REACH entered into force 1 June 2007. As a Regulation it became directly effective in the Member States. The regulation deals with the **Registration, Evaluation, Authorization and Restriction of Chemical substances**. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

The REACH Regulation gives responsibility to industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers will be required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database run by the European Chemicals Agency (ECHA) in Helsinki.

Manufacturers outside the European Union will not have direct obligations under REACH. However, non-European Union manufacturers may appoint an 'only representative' established in the European Union to fulfill the obligations on importers under REACH.

### 2.2.1. General administration

Build up interdisciplinary project groups consisting of representatives from management team, supply management, environmental coordinator, product development, quality management, production manager, safety representative etc.

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## 2.2.2. Roles and responsibilities

REACH distinguishes the following roles in the supply chain:

- Downstream user
- Manufacturer
- Producer of an article
- Supplier of an article
- Distributor

Hitachi PG through its local business units may play several roles under REACH and have specific obligations. Every local business unit must understand their roles and responsibilities under REACH. Responsibility follows the delegation scheme described in country directives with the overall responsibility on LBU manager.

## 2.2.3. Exemptions

REACH covers all substances on their own, in preparations and in articles.

However, REACH does not apply to:

- Radioactive substances (Directive 96/29/Euratom).
- Substances on their own, in preparations or in articles subject to customs supervision and which are in temporary storage for re-exportation or in transit.
- Non-isolated intermediates.
- The carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air.
- Certain substances on their own, in preparations or in articles exempted by Member States in the interests of defense.
- Waste, which as defined in Directive 2006/12/EC, is not a substance according to REACH.

## 2.2.4. Inventory of substances

- Make a list of chemical substances used within your company.
- Collect basic available information on each substance (CAS number, EINECS or ELINCS, classification information etc.).
- Make sure that Safety Data Sheets (SDS) are available for all your substances. SDS should not be older than 3 years.
- Make sure that each substance is used in the way described in the safety data sheet (identified use). Otherwise develop a chemical safety assessment and make a notification to ECHA. Also apply for authorization for using the substance in that way.
- List the substances that are imported from a non-EEA country. Determine the annual volume for each substance from outside EEA (per legal entity).

### Additional information

#### CAS number

Identification of a chemical substance according to the Chemical Abstract Service.

#### EINECS

The EINECS number (European Inventory of Existing Chemical Substances) is a registry number given to each chemical substance commercially available in the European Union between 1 January 1971 and 18 September 1981. An EINECS number is a seven-digit system number of the form 2XX-XXX-X or 3XX-XXX-X, starting at 200-001-8.

#### ELINCS

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As from 19 September 1981, the substances are given an ELINCS number (European List of Notified Chemical Substances). An ELINCS number is a seven-digit system number of the form 4XX-XXX-X, starting at 400-010-9.

#### Classification information

Classification according to CLP, the EU regulation on classification, labelling and packaging of substances and mixtures.

#### EEA

The European Economic Association (EEA) consists of the EU Member States and Iceland, Liechtenstein and Norway.

## 2.2.5. Identification of hazardous substances

Identify hazardous substances (SVHC Substances of very High Concern) in your processes and products by using "Hitachi PG Lists of Prohibited and Restricted Substances".

#### **Additional information**

##### Hitachi PG List of Prohibited and Restricted Substances"

The Hitachi PG Group Instruction GI/SA-01.02A03 "Hitachi PG Lists of Prohibited and Restricted Substances" lists a selection of hazardous substances that are believed to be used in Hitachi PG products, packaging materials or manufacturing processes. <https://library.e.abb.com/public/e208fa696973493bac8938c93429e174/ABB%20List%20of%20Prohibited%20and%20Restricted%20Substances.pdf>

## 2.2.6. Registration

Make sure that the registration requirements are fulfilled by considering the following obligations:

- Registration has to be submitted to ECHA for substances that are manufactured/imported > 1 ton/year (per legal entity).
- Registration has to be submitted to ECHA for substances contained in products if the substance is manufactured/imported > 1 ton/year (per legal entity) and also is intended to be released from the product.
- A chemical safety assessment shall be performed and a chemical safety report completed for all substances manufactured or imported in quantities > 10 ton/year (per legal entity)
- Your identified use must be within the registration.
- If your substance is registered by some actor upstream (e.g. your supplier), make sure that your identified use is within the registration (if the substance is already registered for your identified use, then you do not have to make your own registration).
- If you are outside EEA you may by mutual agreement appoint an "only representative" to fulfill the obligations on importers.
- If you are a manufacturer or importer for the first time of a substance in quantities >1 ton per year you can submit a late pre-registration:
  - At the latest 6 months after manufacturing or importing a substance >1 ton per year.
  - At least 12 months before the relevant transitional deadline for registration.

#### **Additional information**

Registration of in-phase substances > 1 tonne latest 2018-06-01.

Look at <https://echa.europa.eu/information-on-chemicals/registered-substances> in order to see if the substance is already registered for your identified use, then you do not have to make your own registration.

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## 2.2.7. Notification

Make sure that the notification requirement is fulfilled by considering the following obligation:

- Notification of Candidate list substances that are contained in products and that are manufactured/imported > 1 ton/year (per legal entity) has to be submitted to ECHA if the content of respective Candidate list substance is > 0.1 weight-% in the product (producer obligation) or per component (importer obligation). Exemption applies if the substance already is registered or exposure can be excluded.

### Additional information

Look at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances> in order to see if the substance is already registered for your identified use, then you do not have to make any notification.

## 2.2.8. Authorization

Make sure that the authorization requirements are fulfilled by considering the following steps:

- Follow the substance status in Annex XIV. After the sunset date the substance is forbidden within EU (some substances may be accompanied by a list of specific uses that do not require authorization).
- At least 18 months before the sunset date apply for authorization to use a substance
- Contact your suppliers to make sure that an appropriate substitute is available or the identified substances will be authorized for your use.
- Formulate company strategy in regard to substitution for relevant Annex XIV substances.

### Additional information

#### RoI - Registry of Intention list

The RoI list gives an advance warning of the possible inclusion on the Candidate List. (The intention is to develop Annex XV dossiers for the identification of Candidate list substances).

<http://echa.europa.eu/web/guest/registry-of-current-svhc-intentions>

#### Consultation list

Public consultation 45 days – based on Annex XV dossier.

<http://echa.europa.eu/web/guest/proposals-to-identify-substances-of-very-high-concern>

#### Candidate list

Substances identified as meeting the criteria for authorization are included in the Candidate list for eventual inclusion in the authorization procedure.

<http://echa.europa.eu/web/guest/candidate-list-table>

#### Annex XIV – Authorization list

Applications for authorization must be submitted by the company at least 18 months before the sunset date, i.e. the date after which use of the substance in the EU must stop.

<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>

## 2.2.9. Restriction

Make sure that the restriction requirements are fulfilled by considering the following steps:

- Follow the substance status in Annex XVII. Check the conditions for restriction and allowed uses of substances.
- If necessary, start substitution process for Annex XVII substances or reduce the substance content below the stated threshold.

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**Additional information**Annex XVII – Restriction list

Annex XVII contains a list of all restricted substances, specifying which uses are restricted.

<https://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach>

**2.2.10. Communication****Communication with suppliers**

- Have a dialogue with suppliers about your purchased products to check if the content of Candidate list substances is > 0.1 weight-%.
- Have a dialogue with suppliers concerning substances on the Authorization list in Annex XIV
- Check if the supplier will apply for authorization and in that case if the substance(s) will be authorized for your use.
- Ask if an appropriate substitute is available for substances to be prohibited.
- Use the supplier/component risk matrix described in section 5.2 to determine the confidence level of any substances of very high concern being contained within the supplied component based on supplier communications.
- Conduct a collective analysis using the supplier/component risk matrix based on supplied components per product in which to base the Hitachi PG REACH declaration of conformity.
- Inform suppliers about new findings concerning: 1) Dangerous / hazardous properties and/or 2) Insufficient Risk Management Measures.
- Examples of letters to suppliers can be found on Hitachi PG Inside+.

**Communication with customers**

- Provide your customers with sufficient information about Candidate list substances > 0.1 weight-% in products in accordance with Article 33 in REACH.
- The REACH concentration thresholds must be calculated at the component level (judgment of the European Court of Justice, ECJ 2015-09-10).
- Ensure REACH article product declarations are available for all Hitachi PG product supplied to customers on request.
- Submit safety data sheets or other information to the customer.
- Examples of letters to customers can be found on Hitachi PG Inside+.

**Additional information**

Look at Hitachi PG Inside+ in order to find letters to suppliers and customers regarding Candidate list substances in products.

**2.2.11. Classification and labelling**

Importers and manufacturers must notify the classification and labelling of substances placed on the market if the substances are:

- Hazardous substances, on their own or in mixtures and irrespective of the tonnage.
- Subject to registration under the REACH Regulation.

**Additional information**

Classification and labeling is according to CLP regulation 1272/2008 Classification, Labelling and Packaging article 39 & 40.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20170101&from=EN>

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### 2.2.12. Data storage

- Assemble and keep available all the information required to carry out your REACH duties for a period of at least 10 years after the last manufacture, import, supply or use.
- Submit this information or make it available without delay upon request to any competent authority of the Member State where you are established or to ECHA.

### 2.2.13. Strategic positions

- Are there any strategically important substances for which it is difficult to find alternatives?
- Do you use a substance in a way that is not covered by the manufacturer's or importer's chemical safety report, "not identified use"?
- Can you see any potential risk of supply chain disruption?
- Do you have a communication in the supply chain regarding chemicals and the content of chemicals in the products?
- Is there an understanding in the organization of the consequences for business if non-compliant?

## 3. Main obligations for substances in articles

Obligations for substances in articles are considered under previous chapters. The table below is meant to give an illustrative summary of the main obligations for article producers, article importers and article suppliers.

Main obligations for substances in articles

Obligation:	Registration of substances in articles	Notification of substances in articles	Communication of information on substances in articles
legal basis in REACH Regulation	Article 7(1)	Article 7(2)	Article 33
actors concerned	article producers and article importers	article producers and article importers	article suppliers
substances concerned	substances intended to be released from articles	substances included in Candidate List of Substances of Very High Concern for authorisation	substances included in Candidate List of Substances of Very High Concern for authorisation
tonnage threshold	1 tonne per year	1 tonne per year	-
concentration in article threshold	-	0.1% (w/w)	0.1% (w/w)
<b>exemption from obligation possible on the basis of:</b>			
substance already registered for that use	yes	yes	no
exposure can be excluded	no	yes	no

## 4. ECJ Judgement 2015-09-10 concerning substances in articles

Obligations concerning substances in articles are described in Article 7(2) and Article 33 of REACH. Article 7(2) concerns registration and notification of substances in articles. Article 33 describes the duty to communicate information on substances in articles.

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## 4.1. Article 7(2) of REACH

Producer obligation:

- Determine whether a substance of very high concern is present in a concentration above 0.1 weight-% of any article produced.

Importer obligation for a product made up of more than one article:

- Determine for each article whether such a substance is present in a concentration above 0.1 weight-%.

## 4.2. Article 33 of REACH

Supplier obligation for a product with one or more constituent articles containing a substance of very high concern in a concentration above 0.1 weight-% of respective article:

- Inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question.

# 5. Article Compliance Matrix

## 5.1. Background

Obligations according to Article 33:

- The aim of Article 33 is to ensure that sufficient information is communicated with articles to allow for their safe use.
- Producers, importers and other suppliers of articles containing substances of very high concern (SVHC) included on the candidate list for authorization in a concentration above 0.1 weight-% have to provide respective information available to them to the recipients of the articles and as a minimum the name of the substance. This information is to be provided automatically.

According to the judgment of the European Court of Justice (ECJ) from September 10, 2015 that REACH concentration thresholds must be calculated at the component level since ECJ adopted an expansive definition of the term “article” to include objects joined with other objects in order to form more complex products. The effect of this decision is that the SVHC concentration threshold for products must be calculated at the component level.

## 5.2. Communication in supply chain and risk-based approach

- All suppliers to Hitachi PG are obligated to inform Hitachi PG of any SVHC contained within components/products/articles supplied.
- In order for Hitachi PG to verify REACH compliance of its articles and products supplied it first needs to establish REACH compliance of its suppliers and components. The evaluation of suppliers and components can be made by using the matrix shown below.
- Hitachi PG takes a risk based approach through evaluation of the combined risk of both the article and the supplier to ascertain REACH compliance status.
- It is the responsibility of each LBU to complete as necessary an article compliance matrix once relevant components and suppliers have been reviewed.
- The qualification of risk is down to the LBU to determine. Green status only can be classified as REACH compliance. Other risk ratings will trigger the requirement for further supplier dialogue and analysis.

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Supplier category → Component/material ↓ category	Known supplier Good knowledge of REACH	New supplier/ knowledge of REACH  Known supplier/no knowledge of REACH	New supplier/no knowledge of REACH
Low risk Material/ component			
Medium risk Material/ component			
High risk Material/ component			

## 6. Supporting Documents

### 6.1. Regulatory/ statutory requirements

All regulatory and statutory requirements are included in the legal register and/or any relevant addendums within the Management System.

### 6.2. Attachments

n/a

### 6.3. Guidelines

n/a

### 6.4. References

- SA-M-03, Legal and other requirements
- REACH at European Commission [https://ec.europa.eu/growth/sectors/chemicals/reach\\_en](https://ec.europa.eu/growth/sectors/chemicals/reach_en)
- REACH at ECHA <https://echa.europa.eu/regulations/reach>

## 7. Key terms and abbreviations

Key term and abbreviations are available in the Instruction SA-B-01-01 Glossary – Power Grids HSE/SA Management System

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