



ENG-STD-003

G

Instruction to suppliers concerning the placing on the market and use of dangerous substances

To be used as is

DOCUMENT SUMMARY :

This document defines the rules applicable to all Alstom Suppliers relating to the marketing and the use of substances on their own, in mixtures and in articles.

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| ALSTOM | Instructions to Suppliers concerning the placing on the market and use of hazardous substances | Document Reference: ENG-STD-003 Version G | Application date : December 2021 |
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Purpose / Objectives

This document defines the rules applicable to all Alstom Suppliers relating to the marketing and the use of substances on their own, in mixtures and in articles.

Scope of application

The present document is applicable to Alstom Suppliers.

Responsibilities for the execution of this procedure

Accountable: Regions

Responsible for the application: Engineering, Sourcing

Responsible for the compliance: Suppliers

Key Contributors: Supplier Quality, EHS

Activities description

Section 1 – Key principles

This document summarizes the main rules concerning the placing on the market and the use of hazardous substances¹.

These regulations can be summarized in 4 obligations:

- Limit or prohibit the use of certain hazardous substances,
- Inform the users of the risks (employees on-site, maintenance employees, and customers),
- Protect the users (employees and end users),
- Protect the environment.

In order to respect these regulations, Alstom's Suppliers shall prove that the supplies comply with Alstom's requirements and inform Alstom of the presence of any hazardous substances and the risks involved in their use.

Notwithstanding any additional regulations that may apply to transportation of goods, the supplies shall be compliant at any time with the regulation applicable in the location(s) where the supplies are:

- **manufactured AND**
- **delivered according to the agreed Incoterm; AND**
- **used/delivered to the final customer,**

as committed in SCG-FRM-010 and the provisions described in the present document.

Examples of applicable regulation depending on project activities location are given in appendix 6.4.

The Suppliers shall respect the following requirements at any time:

- a. **Requirement 1:** No use of prohibited substances.
- b. **Requirement 2:** No use of substances of concern that may generate risks for Alstom unless a derogation is granted.
- c. **Requirement 3:** To demonstrate conformity, the document ENG-FRM-001 (commitment and declaration on dangerous substances, including the declaration of any other hazardous substances) shall be fulfilled and updated as necessary.

¹ Hazardous substances definition refers to the Globally Harmonized System (GHS) which defines and classifies the hazards of chemical products, and communicates health and safety information on labels and safety data sheets). This non-binding system was adopted by several regions of the world and its adoption is ongoing in other regions. (See appendix 5.8 for more information).

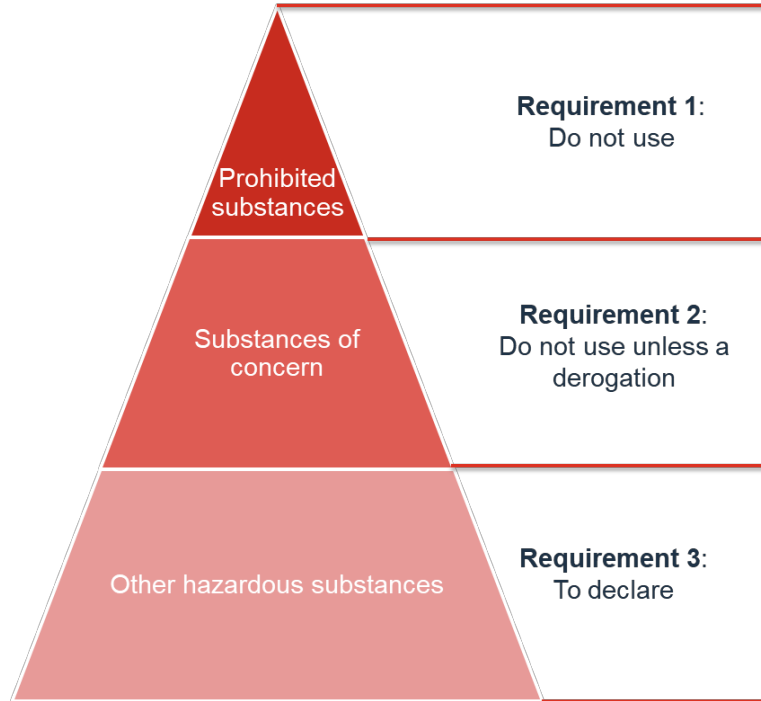


Figure 1 – Essential requirements

Depending on the industrial scheme and location, the Supplier shall refer to the rules defined in the sections 2 (European Economic Area) or 3 (out of European Economic Area).

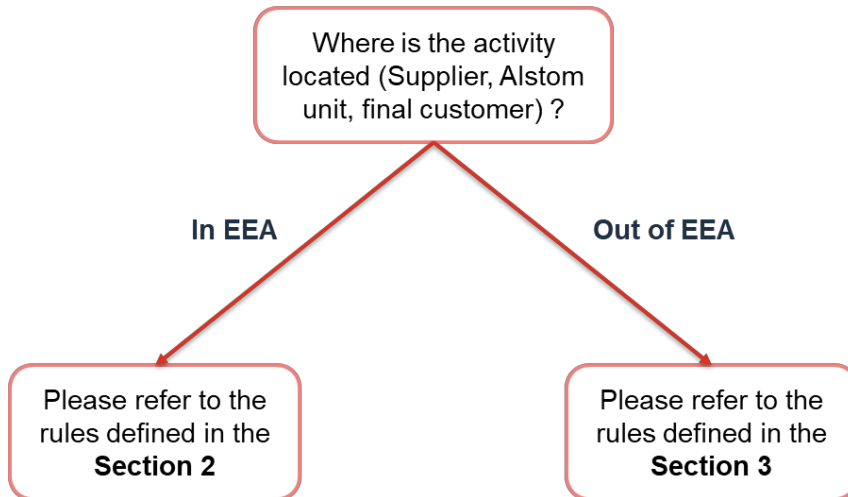


Figure 2 – Flow chart location activities

Section 2 – Rules for European Economic Area (EEA) activities and markets

The Supplier undertakes to respect all the legal and regulatory provisions concerning the placing on the market and the use of certain hazardous substances and especially the provisions concerning the authorization, the communication and the restrictions on the placing on the market and the use of the substances listed in Railway Industry Substance List (RISL, Internet link available in appendix 6.2). This list does not release the Supplier from obligations to comply with other applicable legal and regulatory provisions.

The Supplier undertakes, as soon as the conditions are satisfied, to either register, or have its own suppliers' register the substances, on their own contained in the mixtures and/or contained in the articles which release the substances under normal or reasonably foreseeable conditions of use. The Supplier therefore undertakes to question Alstom to obtain information on its uses and to incorporate this information into the registration files when a Chemical Safety Report is mandatory.

2.1 Requirement 1: No use of prohibited substances

The Supplier undertakes to respect all the legal and regulatory provisions concerning the restrictions on the placing on the market and the use of certain hazardous substances. Most of the substances submitted to prohibition are listed in Railway Industry Substance List (RISL) available on the UNIFE website.

The reference to the RISL does not release the supplier from its obligation to comply with any other applicable legal and regulatory provisions.

2.2 Requirement 2: No use of substances of concern that generate risk for Alstom unless a derogation is provided

- a) The Supplier undertakes not to supply substances or mixtures containing a substance that generates risk for Alstom employees' health during the handling in manufacturing or maintenance of their scope of supply i.e. substances classified as Carcinogenic, Mutagenic or toxic for Reproduction (CMR).
- b) The Supplier undertakes not to supply articles containing a substance that generates risk of supply chain disruption or obsolescence i.e. substances that are submitted to phasing out mechanism and/or that will be prohibited considering location where the supply is manufactured, delivered and used by the final customer.
- c) The Supplier undertakes not to supply articles containing a substance that is legally, regulatory and/or contractually prohibited (on a given project). In the case contractual prohibition applies, Alstom shall inform the supplier about additional requirements.
- d) Specific rules for substances subject to authorization (Annex XIV of REACH)

The lists of substances subject to authorization are published by the European Commission as an amendment of the Annex XIV of REACH regulation.

The substances subject to authorization are also available in the RISL.

- 1) The Supplier undertakes not to supply substances or mixtures containing any substance which is subject to authorization (shown in annex XIV of the REACH regulation), apart from an exception mentioned in d.3).
 - 2) The Supplier undertakes not to supply articles containing a substance listed in annex XIV of the REACH regulation, apart from an exception mentioned in d.3).
 - 3) In the event of an impossibility to comply with clause d.1) or d.2) above, the Supplier undertakes to declare immediately the presence of any substance shown in annex XIV of the REACH regulation. When making the declaration, the Supplier will state the identity of the substance concerned, its SCIP notification number, its quantity (weight percentage), the references of the mixture or the article, containing it and its function inside the mixture or the article concerned. The supplier shall also provide a derogation and a substitution plan according to the template ECO-FRM-001 as well as a commitment to request the authorization from the European Chemical Agency (ECHA) if this is relevant. The substitution plan must include the nature of the new substance or material, the re-qualification tests, and a planning.
After examining the derogation and the substitution plan, Alstom could grant an exception to the clause d.1) or d.2), whilst waiting for the substance to be substituted.
 - 4) The Supplier undertakes to actively monitor the future changes to annex XIV. As soon as a new substance is added, it shall check that the mixture or article delivered does not contain it. The Supplier shall supply a declaration to Alstom immediately after the inclusion of a new substance in annex XIV.
- e) Specific rules concerning Candidate substances for authorization
The lists of substances candidate to authorization are published by the ECHA on its website.
The candidate substances to authorization are available in RISL.
- 1) The Supplier undertakes not to supply substances or mixtures containing a **candidate** substance for authorization **in more than 0.1%* (w/w)** apart from the exception mentioned in e.3) below.
 - 2) The Supplier undertakes not to supply articles containing a **candidate** substance for authorization **in more than 0.1%* (w/w)** apart from the exception mentioned in e.3) below.
 - 3) In the event of an impossibility to comply with clause e.1) or e.2) above, the Supplier undertakes to declare immediately the presence of any substance on the list of candidate substances, **in more than 0.1%* (w/w)**. When making the declaration, the Supplier will state the identity of the substance concerned, its SCIP notification number, its quantity (weight percentage), the references of the mixture, or the article containing it and its function inside the mixture or the article concerned. The supplier shall also provide a derogation and a substitution plan according to the template ECO-FRM-001

as well as a commitment to request the authorization from the ECHA if this is relevant. The substitution plan must include the nature of the new substance or material, the re-qualification tests, and a planning.

After examining the derogation and the substitution plan, Alstom can grant an exception to clause e.1) or e.2), whilst waiting for the substance to be substituted.

* This declarative threshold is not applicable to surface treatments for which the rules apply whatever the content.

- 4) The Supplier undertakes to actively monitor the list of candidate substances for authorization internally. As soon as a new substance is added to it, it shall check that the mixture or article delivered does not contain it. The Supplier shall supply Alstom with a declaration immediately after the inclusion of a new substance on the list of candidate substances for authorization.
 - 5) In addition, if the candidate substance for authorization is placed on the list of substances subject to authorization (annex XIV), the Supplier undertakes to respect the points stipulated in clause "d" above.
- f) Specific rules for Substances of Very High Concern (SVHC) criteria
- 1) The Supplier undertakes not to supply substances or mixtures containing substances with SVHC criteria, except for an exception mentioned in f.3).
 - 2) Criteria for SVHC eligibility are :
 - Substance classified as Carcinogenic, Mutagenic or Toxic for reproduction, category 1 A or 1B, in accordance with the criteria stipulated in the Classification, Labelling & Packaging (CLP) regulation.
 - Substance satisfying the Persistent, Bio accumulative, Toxic, or very Persistent, very Bio accumulative (PBT/vPvB) criteria, as defined in annex XIII of the REACH regulation.
 - Substance presenting concern of equivalent level to those mentioned above, as defined in article 57 (f) of the REACH regulation
 - 3) In the event of an impossibility to comply with clause f.1), the Supplier undertakes to declare immediately the presence of any SVHC in a mixture supplied to Alstom, **in more than 0.1% (w/w)**. When making the declaration, the Supplier will state the identity of the substance concerned, its quantity (weight percentage), the references of the mixture containing it, and its function inside the mixture concerned. The supplier shall also provide a derogation and a substitution plan according to the template ECO-FRM-001.
After examining the derogation and the substitution plan, Alstom can grant an exception to clause f.1), whilst waiting for the substance to be substituted.

2.3 Requirement 3: To demonstrate conformity

During project execution phase, the Supplier shall deliver a written commitment to confirm that its scope of supply respect the requirements 1 and 2, as stipulated in this document. The Supplier shall declare the presence of hazardous substances (according to the GHS rules and designated D(FI) by RISL).

For that purpose, the Supplier must fill-in the document ENG-FRM-001: "Supplier Form: Commitment & Declaration on Hazardous Substances". Other equivalent declarations format could be used after Alstom's approval.

In the case of design change or regulatory modification, the Supplier shall update its commitment and hazardous substances declaration if relevant. The Supplier is responsible of the accuracy of delivered information for all articles supplied.

- a) The Supplier undertakes to appoint a hazardous substances / REACH's representative internally.
- b) The Supplier confirms that it has identified its obligations under the REACH regulation and undertakes to comply with them. It confirms that it will actively monitor the obligations imposed by the REACH and CLP regulations, enabling it to comply with the statutory requirements and those mentioned in the present instruction.
- c) The Supplier undertakes to carry out all necessary actions vis-à-vis its own suppliers in order to guarantee that it complies with the REACH regulation.
- d) The Supplier undertakes to respect all the legal and regulatory provisions concerning the placing on the market and the use of certain hazardous substances.
- e) The Supplier undertakes to notify in the SCIP database the presence of SVHC substances in their products and provides all related information.
- f) The Supplier (of substances or mixtures) supplies all the up-to-date Safety Data Sheets (SDS) and up-to-date exposure scenarios for the substances and mixtures in accordance with the requirements of the REACH Regulation.
- g) The Supplier undertakes to declare the presence of hazardous substances in its scope of supply.

The Supplier declaration must cover:

- 1) Substances which are subject to regulatory restrictions on the placing on the market or the use (listed in annex XVII of the REACH regulation and in the other applicable regulations concerning the restrictions on use of hazardous substances), in other fields of application than those defined by the legislation and present in the mixtures or articles supplied to Alstom in more than 0.1% in mass*.

These substances are identified as P(AR) in the area of restriction and D(FA) in the other fields of application (referring to RISL classification).

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* This declarative threshold is not applicable to surface treatments for which the declaration of hazardous substances is mandatory whatever the content.

- 2) The substances subject to authorization (listed in annex XIV of the REACH regulation), for which Alstom granted an exception, as defined in clause d.3) of point 2.2, and present in the mixtures or articles supplied to Alstom, whatever the concentration of substance in the mixture or article.

These substances are identified as P(AR) after the sunset date and D(FA) before the sunset date (referring to RISL classification).

- 3) The Candidate substances for authorization (list available from the ECHA), for which Alstom granted an exception, as defined in clause e.3) of point 2.2, and present in the mixtures or articles supplied to Alstom in more than 0.1% in mass*. For articles, the weight percentage is calculated on the smallest article that constitutes the supplies and that contains the substance, according the principle: "Once an article, always an article".

These substances are identified as D(FA) (referring to RISL classification).

* This declarative threshold is not applicable to surface treatments for which the declaration of hazardous substances is mandatory whatever the content.

- 4) The substances classified CMR cat 1A & 1B, PBT or vPvB, that could become SVHC, present in the mixtures for which Alstom granted an exception as defined in clause f.3) of point 2.2, or present in any article supplied to Alstom and in more than 0.1% in mass*. For articles, the weight percentage is calculated on the smallest article that constitutes the supplies and that contains the substance, according the scheme: "Once an article, always an article".

These substances are identified as D(FA) (referring to RISL classification).

* This declarative threshold is not applicable to surface treatments for which the declaration of hazardous substances is mandatory whatever the content.

- 5) The substances classified as D(FA) in the RISL (not yet mentioned above), in more than 0,1 % in mass*. For articles, the weight percentage is calculated on the smallest article that constitutes the supplies and that contains the substance, according the scheme: "Once an article, always an article".

* This declarative threshold is not applicable to surface treatments for which the declaration of hazardous substances is mandatory whatever the content.

- 6) Substances which are classified as hazardous in accordance with the criteria stipulated in the regulation (CE) n° 1272/2008 if they are present in the mixtures or articles with thresholds which are higher than the classification thresholds stipulated in the regulation (EC) n° 1272/2008 or by default in more than 0.1 % in mass*. For article, the weight percentage is calculated on the smallest article containing the substance that constitutes the supplies according the scheme "Once an article, always an article".

These substances are identified as D(FI) (referring to RISL classification).

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* This declarative threshold is not applicable to surface treatments for which the declaration of hazardous substances is mandatory whatever the content.

2.4 Additional requirements for Suppliers belonging to a nonmember country of the EEA supplying in EEA

The Suppliers that do not belong to EEA undertake to comply with all the clauses in section 2.1, 2.2 and 2.3.

The Suppliers of substances, mixtures and articles which release the substances under normal or reasonably foreseeable conditions of use of nonmember countries of the EEA shall appoint an "Only representative" based in Europe as defined in the REACH regulation. This "Only Representative" based in the EEA will be responsible for registration and authorization procedures under the REACH regulation for the substances supplied to Alstom, substances on their own, in mixtures or in articles which release the substances under normal or reasonably foreseeable conditions of use. The Suppliers from nonmember countries of the European Economic Area shall supply the identity and the contact details of their "Only Representative" to Alstom.

Section 3 – Rules for Non-European Economic Area activities and markets

3.1 Requirement 1: No use of prohibited substances

The Supplier undertakes to respect all the legal and regulatory provisions concerning the restrictions on the placing on the market and the use of certain hazardous substances. The applicable regulations that apply are those where the supply is manufactured, delivered according to agreed Incoterm and used by the final customer.

Most of the substances submitted to prohibition are listed in Railway Industry Substance List (RISL) available on the UNIFE website.

The restrictions on the use of certain hazardous substances P(AR) are listed in the RISL that could be enlarged by ALSTOM considering local provisions and further restrictions.

The reference to the RISL does not release the Supplier from obligations to comply with any other applicable regulatory provisions.

3.2 Requirement 2: No use of substances of concern that generate risk for Alstom unless a derogation is provided.

- a) The Supplier undertakes not to supply substances or mixtures containing a substance that generates risk for Alstom employees' health during the handling in manufacturing or maintenance of their scope of supply i.e. substances classified as Carcinogenic, Mutagenic or toxic for Reproduction (CMR).
- b) The Supplier undertakes not to supply articles containing a substance generates that risk of supply chain disruption or obsolescence i.e. substances that are submitted to phasing out mechanism and/or that will be prohibited considering location where the supply is manufactured, delivered to Alstom and used by the final customer.
- c) The Supplier undertakes not to supply articles containing a substance that is legally, regulatory and/or contractually prohibited (on a given project). In the case contractual prohibition applies, Alstom shall inform the supplier about additional requirements on project.
- d) In the event of an impossibility to comply with clause a, or b, or c the Supplier undertakes to declare immediately the presence of the substance of concern. When making the declaration, the Supplier will state the identity of the substance concerned, its quantity (weight percentage), the references of the mixture containing it, and its function inside the mixture concerned. The supplier shall also provide a derogation and a substitution plan according to the template ECO-FRM-001. After examining the derogation and a substitution plan, Alstom can grant an exception in writing to clause a) or b), whilst waiting for the substance to be substituted.

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3.3 Requirement 3: Demonstration of conformity

During project execution phase, each Supplier shall deliver a written commitment to confirm that its scope of supply respect the requirement 1 and 2, as stipulated in this document. The Supplier shall declare the presence of hazardous substances (according to the GHS rules and designated D(FI) by RISL).

For that purpose, the Supplier must fill-in the document ENG-FRM-001: "Supplier Form: Commitment & Declaration on Hazardous Substances". Other equivalent declarations format could be used after Alstom Approval.

In the case of design change or regulatory modification, the Supplier shall update its commitment & declaration on hazardous substances if relevant. The Supplier is responsible of the accuracy of delivered information for all supplies.

Alstom strongly recommends to declare the presence of hazardous substances applying the threshold limit at 0.1% in mass relating to the smallest article that constitutes the supplies and that contains the substance, according the scheme: "Once an article, always an article".

The Supplier commitment and declaration must cover the points:

- a) The Supplier undertakes to appoint a contact responsible of hazardous substances internally.
- b) The Supplier confirms that it has identified its obligations under Hazardous substances regulations and undertakes to comply with them. It confirms that it will actively monitor the obligations imposed by applicable regulations enabling it to comply with the statutory requirements and those mentioned in the present instruction.
- c) The Supplier undertakes to carry out all necessary actions vis-à-vis its own suppliers in order to guarantee that it complies with the Hazardous substances regulations.
- d) The Supplier undertakes to respect all the legal and regulatory provisions concerning the placing on the market and the use of certain hazardous substances.
- e) The Supplier (of substances or mixtures) supplies all the up-to-date SDS and up-to-date exposure scenarios for the substances and mixtures in accordance with the requirements of hazardous substances regulations
- f) The Supplier undertakes to declare the presence of hazardous substances in its scope of supply.

Section 4 – Definitions

4.1 General definitions

For the purpose of this document the following definitions shall apply:

- **Article** means:
An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
- **Chemical Safety Report** means:
The chemical safety report documents the chemical safety assessment undertaken as part of the REACH registration process, and is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios.
- **D(FA)** means:
“Declarable for Assessment”
- **D(FI)** means:
“Declarable For Information”
- **ECHA** means :
The European Chemical Agency based in Helsinki which was set up by the REACH regulation.
- **European Economic Area** means :
The area defined in the European Economic Area agreement dated January 1st, 1994 according to which the movement of persons, goods, services and capital are free within the European single market. As of today this area comprises the members of the European Union and three of the members of the European Free Trade Association (EFTA): Iceland, Norway and Liechtenstein. For further information: www.efta.int/eea.
- **Incoterm** means :
An abbreviation for International Commercial Terms. They are a set of rules which define the responsibilities of sellers and buyers for the delivery of goods under sales contracts for domestic and international trade. They are published by the International Chamber of Commerce (ICC) and are widely used in international commercial transactions. The first Incoterms® were issued in 1936. The most recent version of Incoterms®, Incoterms® 2010, were launched in September 2010 and became effective January 1, 2011.
- **Mixture** means :
A mixture or solution composed of two or more substances”.
- **Only representative** means :

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Any physical or legal person which is established in the Community in order to perform, as an exclusive representative, importers obligations under the REACH regulation.

- **PBT** substance means :
Any substance satisfying the criteria stipulated in annex XIII of the REACH Regulation as being Persistent, Bioaccumulative, and Toxic.
- **P(AR)** means:
“Prohibited in Area of Restriction” and corresponds to codifications applied in “Railway Industry Substance List”. It means that the substance cannot be used under specified conditions.
- **ROHS** means :
“Restriction of the use Of certain Hazardous Substances in electrical and electronic equipment” .
- **Substance** means:
a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.
- **Sunset date** means:
Annex XIV (list of substances subject to Authorization) will specify for each substance included in that Annex a date (called ‘the sunset date”) from which the placing on the market and the use of that substance will be prohibited.
- **Supplier** means:
Alstom’s supplier, vendor, consultant, distributor, service provider and/or subcontractor.
- **vPvB** substance means :
Any substance satisfying the criteria stipulated in annex XIII of the REACH Regulation as being Very Persistent, Very Bioaccumulative.

4.2 Definitions relating to substances which are prohibited / subject to restrictions / subject to declaration

- **Substances which are subject to the regulatory restrictions applicable to the placing on the market or the use:**
In this case, restriction means prohibition in specific fields of application. The materials and substances on this list shall not be used in the stipulated restricted field.
- **Substances subject to authorization:**
A list of substances subject to authorization is stipulated in annex XIV of the REACH regulation.

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It is prohibited to use a substance which is subject to authorization without an authorization from the ECHA. This list of substances is regularly updated and is compiled from the list of candidate substances for authorization.

- **Candidate substances for authorization:**

The list of candidate substances for authorization is available on the ECHA website.

It is mandatory to notify the ECHA or its professional recipients of the presence of SVHC in articles under certain conditions. This list is regularly updated and is compiled from all substances with SVHC criteria.

- **SVHC Criteria:**

- Substance classified as Carcinogenic, Mutagenic or Toxic for reproduction, category 1 A or 1B, in accordance with the criteria stipulated in the CLP regulation.
- Substance satisfying the PBT/vPvB criteria (Persistent, Bioaccumulative, Toxic, or very Persistent, very Bioaccumulative), as defined in annex XIII of the REACH regulation.
- Substance presenting concern of equivalent level to those mentioned above, as defined in 'article 57 (f) of the REACH regulation.

- **Hazardous substances:**

In accordance GHS and CLP.

Section 5 – Abstract

The table below summarizes the scope of application of each essential requirement and associated rules.

| Requirement N° | Applicable To | Correspondance with RISL category | Rules |
|------------------------|--|--|--|
| Requirement 1 | Prohibited substances i.e. prohibited by regulations. | Prohibited in Area of Restriction (P(AR)) in RISL (Railways Industry Substance List) and local further prohibition. | ⇒ Strictly prohibited. |
| Requirement 2 | Substances of concern (that could lead on issues) i.e. substances or mixtures that generates risk of exposure when used in Alstom manufacturing units and substances that are submitted to phasing out mechanism and/or that will be prohibited. | Declarable For Assessment (D(FA)) in RISL (Railways Industry Substance List) and specific requirement if any declared by Alstom (Customer specific requirement). | ⇒ Prohibited unless a dispensation granted by ALSTOM in writing. If used: to declare, to assess conjointly by the Supplier and ALSTOM regarding the risk level (legal context and industrial scheme). Depends on Supplier location and the Project Industrial Operation (PIO). |
| Requirement 3 : | Other hazardous substances i.e. substances classified hazardous according to the GHS rules (CLP in European Economic Area). | Declarable For Information (D(FI)) in RISL (Railways Industry Substance List). | ⇒ To declare so that the compliance could be demonstrated and further prohibition could be anticipated. |

Section 6 – Appendices

6.1.1 Regulatory context (not exhaustive and for description purpose only)

6.1.1.1 European Economic Area context

- The Regulation (EC) No 1907/2006, known as the REACH Regulation (Registration, Evaluation & Authorization of CHemicals) came into force in June 2007. This regulation which is applicable in the European Economic Area, lays down obligations to the manufacture, the placing on the market, the use and prohibition of substances.
 - The manufacturers and importers of chemical substances shall, under certain conditions, register their substances. This involves identifying their dangers and evaluating the risks of using them throughout their life cycle.
 - The substances which cause the most concern called SVHC (Substances of Very High Concern) are subject to authorization provisions, restriction on the use and/or duties to communicate, whether they are present in mixtures or in the articles.

The principal provisions and deadlines concerning this regulation are set out in Appendix 6.6.

- The Regulation (EC) No 1272/2008, known as the CLP Regulation (Classification, Labelling & Packaging) came into force in January 2009. This regulation lays down obligations to be respected concerning the classification, labelling and packaging of chemical products.
- The directive 2011/65/EU, known as the RoHS directive – relating to the restriction of the use of hazardous substances in electrical and electronic equipment entered into force on 21 July 2011. This Directive lays down rules on the restriction of the use of certain substances (Cadmium, Mercury, Chromium VI, Lead, PBB, PBDE). Further substances could be concerned (HBCDD, 3 phtalates).
- The Waste Frame Directive (EU) 2008/98/EC, revised 2018/851/EU amendment on the SCIP database came into force on January 5th, 2021.
- The regulation (EU) N° 517/2014, known as fluorinated greenhouse gases Regulation came into force on 1st January 2015. The purpose of this Regulation is to protect the environment by reducing emissions of fluorinated greenhouse gases. This regulation established:
 - Rules on containment, use, recovery and destruction of fluorinated greenhouse gases,
 - Conditions on the placing on the market of specific products and equipment that contain fluorinated greenhouse gases,
 - Conditions on specific uses of fluorinated greenhouse gases,
 - Quantitative limits for the placing on the market of hydrofluorocarbons.
- The regulation (EU) N° 528/2012, known as Biocide Product Regulation, entered into force on 1st September 2013. The new Regulation on biocidal products contains provisions which apply not only to biocidal products but also to all articles considered as a “treated article”. A Treated Article (also imported article) is a substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

6.1.1.2 Non-European Economic Area context

The list of regulatory references below is not exhaustive.

- **Australia:** NOHSC: 1011 (1995) National Model Regulation for the Control of Scheduled Carcinogenic Substances.
- **Canada:** The Canadian Environmental Protection Act, 1999 (CEPA), "An Act respecting pollution prevention and the protection of the environment and human health in order to contribute to sustainable development".
CEPA includes in particular the regulation SOR/DOR/2012-285 "Prohibition of Certain Toxic Substances Regulations, 2012".
- **China:**
 - China Reach: Provisions on the Environmental Administration of New Chemical Substances in China (2010),
 - China RoHS.
- **India:**
 - India RoHS,
 - Environment Protection Act / Factories Act / Manufacture, Storage and Import of Hazardous Chemicals 1989 ("Rule 1989").
- **Russia:** Federal law n° 52-fz.
- **South Africa:**
 - R 341: Regulations for the prohibition of the use, manufacturing import and export of asbestos and asbestos containing materials 2008,
 - R586: Machinery and occupational safety Act, (ACT No. 6 OF 1983) Lead Regulations,
 - R 1179: Hazardous Chemical Substances Regulations, 1995.
- **South America:** Several ordinances.
- **Saudi Arabia:**
 - General Environmental law, issued by the Royal Decree N° 34 dated 28/7/1422H corresponding to 16/10/2001.
- **Switzerland:**

Since Switzerland is not a member of the EU or the European Economic Area (EEA), EU REACH regulation does not apply in this country.

Switzerland has its own chemical regulations adopting REACH-like registration requirements, and SVHC in articles communication duties.

The provisions governing the obligation to notify, declare and register new substances and provisions governing the obligation to communicate the presence of Substances of Very High Concern (SVHC)- REACH Candidates list, are contained in its Chemicals Ordinance on Protection against Hazardous Substances and Preparations (known as ChemO).

Anyone who commercially supplies an article containing a substance of very high concern in a concentration greater than 0.1% by weight must provide a declaration to the customer.

The provisions on the restriction of the marketing and uses of certain substances, preparations and articles are governed by another ordinance Chemical Risk Reduce Ordinance (ORRChem).
- **United Kingdom:**

Since January 31, 2021 United Kingdom left the European Union and apply former EU regulation/directive in their own laws.

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- UK Registration, Evaluation, Authorisation & restriction of Chemicals (REACH) came into force in January 2021
- GB CLP regulation
- UK RoHS
- **USA:**
 - Toxic Substances Control Act: 40 CFR (Code of Federal Regulation) cover EPA (Environmental Protection Agency) mission on protection Human Health & Environment protection,
 - Prop 65 California (official name: Safe Drinking Water and Toxic Enforcement Act of 1986) requires businesses to inform Californians about exposures to chemicals known to cause cancer, birth defects or other reproductive harm.

6.2 Railway Industry Substance List (RISL)

To help the Suppliers to realize their substances declaration, the Railway Industries, represented by UNIFE, have put in place a substances list (RISL). This list is available on the UNIFE website.

This list will be regularly updated, but it does not relieve the Suppliers of their responsibilities regarding the legal obligations.

The substances subject to restriction or legal provisions were taken up in this list, and associated to codes (UNIFE Categories). The details of codification are described below:

a) Prohibited in Area of Restriction [Acronym = P(AR)]

A substance classified as Prohibited shall not be present in finished goods, parts or components, defined in the "area of restriction" field. This is applicable to the entire scope of supply. This classification is due to legal prohibition provisions and these substances shall not be present in the delivery in that area. It must be noted that in some cases the same substance may be classified as "Prohibited" in a given area of restriction and as "Declarable for Assessment" in all other applications.

b) Declarable

A substance classified as Declarable shall be declared in writing to the customer prior to delivery if present in the scope of supply. Declarable substances are separated into two categories:

1) Declarable for Assessment [Acronym= D(FA)]

A substance classified as Declarable for Assessment shall not be present in the scope of supply unless assessment for use has been granted by the customer. If the scope of supply contains a D(FA) Substance, a derogation shall be requested and granted by the customer prior to delivery of the goods.

It must be noted that in some cases the same substance may be classified as "Prohibited" in a given area of restriction and as Declarable for Assessment in all other applications

2) Declarable for Information [Acronym= D(FI)]

A substance classified as D(FI) shall be declared to the customer for their information. All substances that are not listed in the UNIFE database and that are classified as "Hazardous" according to the CLP Regulation (Regulation (EC) No 1272/2008 on Classification, Labeling and Packaging of substances and mixtures) shall be considered as D(FI).

6.3 Guideline for the Suppliers (without prejudice to other provisions of these instructions)

How to identify hazardous substances in a chemical preparation?

Safety Data Sheet (SDS) provides information about the hazards of a product and advice about safety precaution. That document includes the list of hazardous material or substance of the product (Section 3 according to GHS: Globally Harmonized System of Classification and Labelling of Chemicals).

Example:

| Section 3: Composition/information on ingredients | | | |
|---|----------------|----------------------------|---|
| 3.1 Substances | | | |
| CAS No. | Substance Name | Content in percent w/w (%) | GHS Classification |
| 77777-77-1 | Substance 1 | 30% | Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 |
| 88888-88-1 | Substance 2 | 20% | Acute tox. 4 (Oral), H302 Eye Irrit. 2A, H319 |

Figure 3 – Extract from section 3 of a Safety Data Sheet

How to identify hazardous substances in an article?

Most of hazardous substances of articles are chemical products that are used to manufacture the article (surface treatment, flame retardant, plasticizer, color, additive, etc.). The way to identify hazardous substances is:

- ⇒ to get information from Safety Data Sheet those chemical products.(substances and mixtures)
- ⇒ to request information on the potential presence of hazardous substances in article to article Supplier

How to get information from Suppliers?

An article may have several steps of manufacturing along its supply chain. That underlines the necessity to forward this requirement to Suppliers at every tier and recover hazardous substances information through tier-1 suppliers.

Principle:

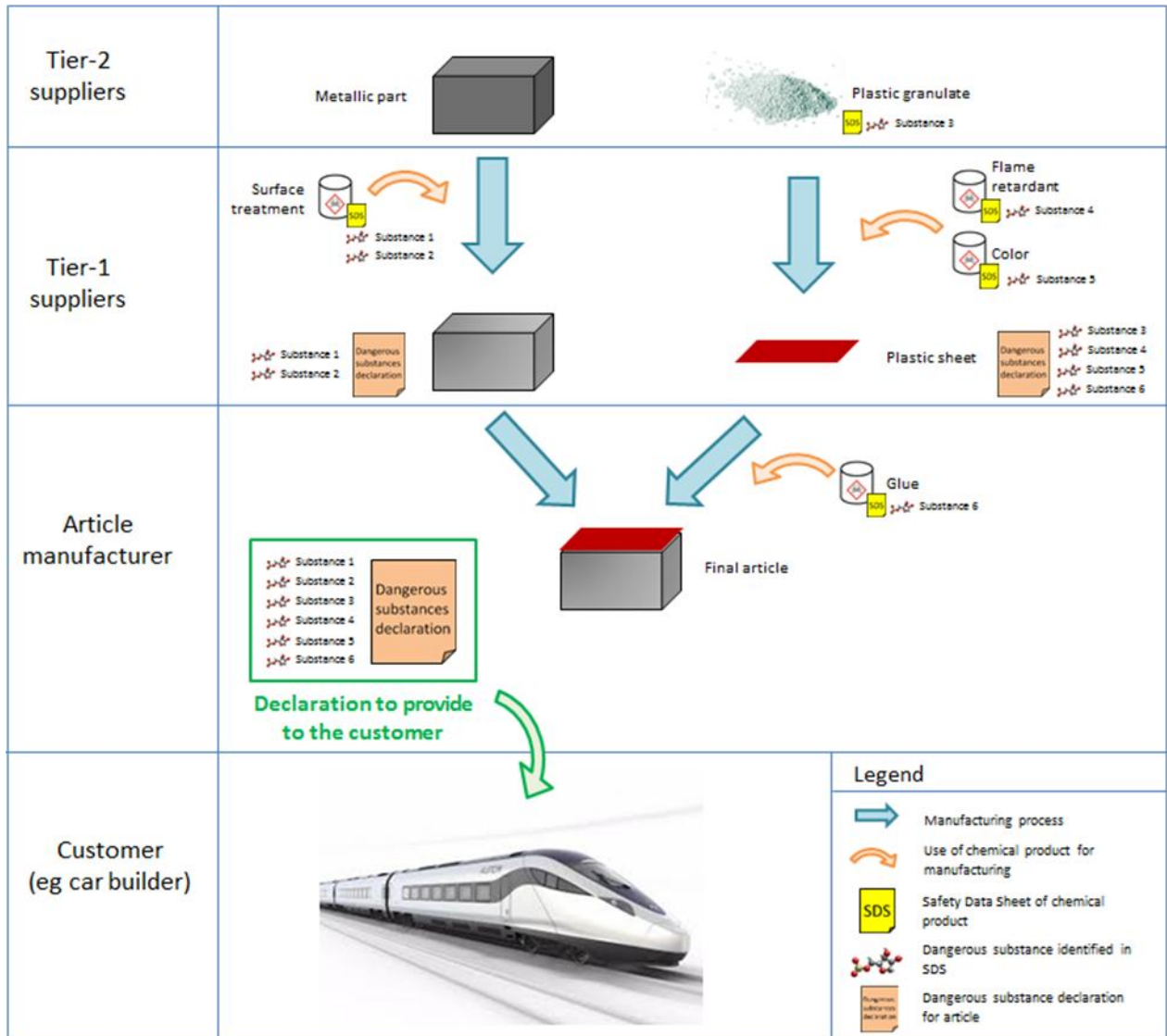


Figure 4 – Principle for collecting hazardous substances information

6.4 Examples of industrial schemes

- Example n°1
 - The Supplier is based in the US
 - Delivery of goods done to Alstom Hornell (US)
 - Final customer in South Africa.

The Supplier has to follow regulations of the US and South Africa.

He is requested to commit by signing the "SCG-FRM-010 commitment" (meaning that he commits to respect the local applicable regulations).

He is requested to declare both first two sheets in the ENG-FRM-001 in which he will confirm that he will indeed respect US and South Africa applicable regulations. He will also be expected to declare substances.

- Example n°2
 - The Supplier is based in India
 - Delivery of goods done to Alstom KTW (Poland)
 - Final customer in France.

The applicable regulations are those of India and the European Union (REACH). The Supplier has to follow regulations of India and Europe.

He is requested to commit by signing the "SCG-FRM-010 commitment" (meaning that he commits to respect the local applicable regulations).

He is requested to declare both first two sheets in the ENG-FRM-001 in which he will confirm that he will indeed respect India and EU regulations. He is expected to declare substances and SVHC substitutions according to ENG-STD-003.

In this case, Alstom has to declare to final customer the list of substances and concerned components.

- Example n°3
 - The Supplier is based in France
 - Delivers to Hornell (US)
 - Final customer is Amtrak (US).

The applicable regulations are those of the EU and US.

He is requested to commit by signing the "SCG-FRM-010 commitment" (meaning that he commits to respect the local applicable regulations).

He is requested to declare both first two sheets in the ENG-FRM-001 in which he will confirm that he will indeed respect EU and US applicable regulations. He will also be expected to declare substances and SVHC substitutions according to ENG-STD-003 instructions. (In this case, the obligation of declaration is requested by the final customer).

6.5 Legal provisions and deadlines stipulated in the REACH regulation

| 2007 | |
|---------------------------|---|
| 1 June 2007 | REACH entered into force. Title IV REACH "Communication in the supply chain" applies. |
| 2008 | |
| By 1 June 2008 | <ul style="list-style-type: none"> • Registration of non phase-in substances on their own, in mixtures or intended to be released from articles before they are manufactured/imported/put on the market. • Title V REACH "Downstream User's obligations" applies. • Title VII REACH "Authorization" applies, including procedures establishing candidate list for authorization (Article 59 REACH). • Duty to communicate information on substances of very high concern present in articles and included in the candidate list to article recipient/consumer upon request under certain conditions (Article 33 REACH). • Title IX REACH "fees and charges" applies. |
| 2009 | |
| By 1 January 2009 | <ul style="list-style-type: none"> • Publication on Agency website of pre-registered phase-in substances with first envisaged registration deadline (Article 28.4 REACH). • First recommendation for a priority list of substances for authorisation to be issued by the Agency (Article 58.3 REACH). |
| By 1 June 2009 | Title VIII REACH "Restrictions" applies – repeal of Directive 76/769/EEC. |
| 2010 | |
| From 1 June 2008 until | • Registration of: |

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| | |
|------------------------------------|---|
| 30 November 2010 | <ul style="list-style-type: none"> - Substances classified as “CMR”, category 1 and 2 in quantities of 1 tonne/year and above per manufacturer/importer. - Substances classified as very toxic to aquatic organisms (R50/53) in quantities of 100 tonnes/year and above per manufacturer/importer. - Other substances on their own, in mixtures or intended to be released from articles in quantities of 1000 tonnes/year and above per manufacturer/importer (Article 23.1 REACH). |
| 2011 | |
| As of 1 June 2011 | <ul style="list-style-type: none"> • Notification of substances in articles (Article 7.2 REACH) 6 months after they have been included in the candidate list (Article 7.8 REACH). <p>Warning: Information requirements to Downstream Users apply as of inclusion on the candidate list</p> |
| 2013 | |
| From 1 June 2008 until 31 May 2013 | <ul style="list-style-type: none"> • Registration of substances on their own, in mixtures or intended to be released from articles in quantities of 100 tonnes/year and above per manufacturer/importer (Article 23.2 REACH). |
| 2018 | |
| From 1 June 2008 until 31 May 2018 | <ul style="list-style-type: none"> • Registration of substances on their own, in mixtures or intended to be released from articles in quantities of 1 tonne/year and above per manufacturer/importer (Article 23.3 REACH). |

6.6 Globally Harmonized System

Globally Harmonized System of Classification and Labelling of Chemicals (GHS) defines and classifies the hazards of chemical products, and communicates health and safety information on labels and safety data sheets).

The two major elements of GHS are:

- a) **Classification of the hazards of chemicals according to the GHS rules:** GHS provides guidance on classifying pure chemicals and mixtures according to its criteria or rules.

- b) **Communication of the hazards and precautionary information** using Safety Data Sheets and labels:
- **Labels** - With the GHS, certain information will appear on the label. For example, the chemical identity may be required. Standardized hazard statements, signal words and symbols will appear on the label according to the classification of that chemical or mixture. Precautionary statements may also be required, if adopted by your regulatory authority.
 - **Safety Data Sheets (SDS)** - The GHS SDS has 16 sections in a set order, and minimum information is prescribed.

An extract of Adoption Text of GHS are presented in the table below:

| Countries/Continent | Texts references |
|---------------------|--|
| Argentina | Resolution N° 801/2015 of 10 April 2015 and Resolution SRT 3359/2015 of 29 September 2015 |
| Australia | Model Work Health and Safety (WHS) laws |
| Canada | Hazardous Products Regulations, Canada Gazette, Part II on February 11, 2015 |
| China | 28 GHS compulsory national standards (GB 30000-2013) |
| Europe | EU Classification, Labelling and Packaging (CLP) regulations |
| Japan | Industrial Safety and Health Law (ISHL) and Law concerning Pollutant Release and Transfer Register (PRTR) and Safety Data Sheet (SDS) systems and Chemical Substances Control Law (CSCL) |
| Russia | Technical Regulation of Customs Union "On safety of chemical products" and compulsory national standards GOST |
| South Africa | Hazardous Chemical Substances Regulations (1995) national standard on the GHS (SANS 10234:2008 - "Globally Harmonized System of classification and labelling of chemicals") |
| Switzerland | Supply and Use (Chemicals law and chemicals ordinance). SR 813.11 (on chemicals) and SR 813.12 (on biocidal products) |
| USA | Hazard Communication Standard (HCS) |

A – References

The following documents are referenced through the text.

A-1 Parent documents

[P1] ECO-WMS-004 Hazardous substances macro-process

A-2 Child documents

[C1] ENG-FRM-001 Supplier Form: Commitment & Declaration on Hazardous Substances

[C2] ECO-FRM-001..... Hazardous substances derogation and substitution plan template

A-3 Records generated and maintained

During the normal application of this Instruction the following records will be generated and maintained:

| Record Name | Form number | Record type | Access | Location | Owner | Validating Function | Retention Time |
|---|-------------|-------------|------------|----------|----------|-----------------------|----------------|
| Supplier Form: Commitment & Declaration on Hazardous Substances | ENG-FRM-001 | Declaration | Restricted | MaDaM | Supplier | Ecodesign Engineering | Undetermined |
| Hazardous substances derogation and substitution plan template | ECO-FRM-001 | Derogation | Restricted | MaDaM | Supplier | Ecodesign Engineering | Undetermined |

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B – Control Sheet

| Version | Date | Content of Modification | Author(s) |
|----------------|---------------|---|---------------------|
| 01 | May 2008 | Update Cancel and replace DEV-STD-005 | Alexandre MOTTEUX |
| 02 | Sept 2008 | Scope Responsible Execution | Véronique ANDRIES |
| 03 | Dec 2009 | Major modification | Inham OUJADOU |
| 04 | August 2011 | Major modification | Inham OUJADOU |
| F | October 2016 | Major revision | Gwenaëlle GRANVORKA |
| G | December 2021 | Adding of SCIP content and derogation/substitution template | Fabien LE NY |

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