Railways Industry Substance List Guidelines

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About UNIFE

Operating in Brussels since 1992, UNIFE, the *European Rail Supply Industry Association*, represents European train builders and rail equipment suppliers. The association advocates for more than 110 of Europe's leading rail supply companies – from SMEs to major industrial champions – active in designing, manufacturing, maintaining and refurbishing rail transport systems (trains, metros, trams, freight wagons), subsystems and related equipment. UNIFE also brings together national rail industry associations from 12 European countries. UNIFE members have an 84% market share in Europe and supply 46% of the worldwide rail production, representing more than 400,000 jobs in Europe.

The UNIFE Chemical Risks Topical Group (CR TG) leads UNIFE's policy on chemicals and hazardous substances management at the world and European levels, including the *European Chemicals Agency* (ECHA) activities, but not limited to them. It focuses on batteries, F-Gases (fluorinated gases), OHS (occupational health and safety), PFAS (Per- and polyfluoroalkyl substances), REACH (Registration, Evaluation, Authorization and restriction of Chemicals), RoHS (Restriction of Hazardous Substances), SCIP (substances of concern in products), and WEEE (waste electrical and electronic equipment). It updates the **Railway Industry Substance List (RISL)**.

About RISL

The benefit of a joint industry approach is improved control of the composition of products from increased transparency and harmonised flow of information through the supply chain. This is necessary for improving the environmental performance of rail products, providing proof for legal environmental compliance, and as a base for further assessment. Advanced product knowledge can also lead to reduced costs for maintenance and end-of-life activities.

UNIFE has developed the **Railway Industry Substance List (RISL)**, which shows the substance controls applicable to the railway industry in the European Union, Australia, Canada, the United Kingdom (UK), the United States of America (USA), and Switzerland.

The exhaustive list of regulations included in the RISL is the following:

European Economic Area (including the European Union)

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP);
- Regulation (EU) 2019/1021 on persistent organic pollutants (POPs);
- Regulation (EU) 2024/590 on substances that deplete the ozone layer (OzDS);
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2);
- Directive (EU) 2015/863 as regards the list of restricted substances (RoHS 3);
- Directive 2000/53/EC on end-of-life vehicles;
- Regulation (EU) 2023/1542 concerning batteries and waste batteries;
- Regulation (EU) 2024/573 on fluorinated greenhouse gases;
- Regulation (EU) 2017/852 on mercury.

Australia

- Australian Work Health and Safety Regulations (SLI No. 262, 2011).

Canada

- Canadian National Pollutant Release Inventory (CAN NRPI);
- Canadian Toxic Substance List;
- Canadian (SOR/2012-285) Prohibition of Certain Toxic Substances Regulations.

United Kingdom

- UK registration, evaluation, authorisation and restriction of chemicals (UK REACH).

Switzerland

- Swiss Regulation (SR 814.81) on the Reduction of Risks relating to the Use of Certain Particularly Dangerous Substances, Preparations and Articles (Chemical Risk Reduction Ordinance, ORRChem).

United States of America

- US Code Federal Regulations (US 40 CFR) on Protection of Environment;
- 40 CFR Part 705 on Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances;
- 40 CFR Ch. (7-1-10 Edition) #372,65(a) on Chemicals and chemical categories to which this part applies.

The RISL separates substances into prohibited in the area of restriction, declarable for assessment (that shall be avoided), and declarable for information. It aims to inform suppliers and sub-suppliers about which materials and substances must not or should not be used.

UNIFE established this document to help SMEs understand how to apply the RISL and comply with European legislation.

RISL structure

The **Railway Industry Substance List (RISL)** presents information on:

- Substances name and their identification number (CAS & EINECS);
- RISL Category, which aims at specifying restrictions on the use and declaration of presence rules;
- Controlled applications, which aim at specifying areas of restrictions;
- Legislation references, which aim to deliver reasons for restrictions;
- Modification date.

RISL definitions

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"[1]. Following the judgement of the Court of Justice of the European Union, there is no need to distinguish between articles incorporated as a component of a complex product and articles presented in an isolated manner. Therefore, a sub-article should follow the "once an article, always an article" principle.[2]

CAS registry number: it is the identification number of the "*Chemical Abstracts Service*". The number presents a unique numeric identifier containing up to 10 digits, divided by hyphens into three parts: "XXXXXX-XX-X". The right-most digit is a check digit used to verify the validity and uniqueness of the entire number. The number is typed in with the hyphen "-".

EINECS number: the EC inventory numbers are registered from EINECS (*European Inventory of Existing Commercial Chemical Substances*) and ELINCS (*European List of Notified Chemical Substances*). Both numbers have the general form "XXX-XXX-X". The number is typed in with the hyphen "-".

Legislation references: the format depends on the region of the world and countries. For instance, the official EU text can be consulted at the appropriate website: http://eur-lex.europa.eu/.

Material: is the substance (or substances) of which an object is made or composed. Composite materials are made from more constituent materials.

Mixture: it "means a mixture or solution composed of two or more substances".[3]

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".[4]

[1] According to the article 3 (3) of the REACH regulation - 1907/2006.
[2] Court of Justice of the European Union - 10 September 2015 - Judgment in Case C-106/14 Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) v Ministre de l'Écologie, du Développement durable et de l'Énergie
[3] According to the article 3 (2) of the REACH regulation - 1907/2006.
[4] According to the article 3 (1) of the REACH regulation - 1907/2006.

RISL category field

Prohibited (in Area of Restriction): **Acronym: P(AR)**

A substance classified as Prohibited (in the Area of Restriction) shall comply with the restrictions specified in the "Controlled applications" field. The limit value for compliance is 0.1 % w/w per article as part of a complex article in a material or mixture unless otherwise specified in the RISL (for example, RoHS or the Battery regulation). In all other applications or below the compliance limit value, a substance shall be regarded as a Declarable Substance.

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

Declarable for Assessment: **Acronym: D (FA)**

A substance classified as Declarable for Assessment shall not be present in the scope of supply unless the customer has given approval. The limit value for a substance declarable for assessment is 0.1 % w/w in a material or mixture unless otherwise specified in the RISL. Approval is required before delivery of the goods. If a declarable substance is present in the scope of delivery and exceeds the permitted limit value, a phase-out plan to eliminate the substance shall be agreed upon between the customer and the supplier, depending on each company's policy. All Declarable Substances shall be declared for the supplied article using the UNIFE Material and Substance Declaration template.

It is crucial to consider the surface coating layer (treatment, paints, etc.) separately regarding content and limit values. For instance, the REACH regulation authorises the use of nickel if no skin contact is expected.

Declarable for Information: **Acronym: D (FI)**

A substance classified as Declarable for Information D(FI) shall be declared if known to be present with a relevant mass (above 0.1 % w/w) per article as part of a complex article in the scope of supply. Declarable for Information D(FI) includes all substances that are not listed as P(AR) and D(FA) and that are classified as "Hazardous" according to the CLP regulation.[5]

[5] Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures.

How to use the RISL during parts and components design?

Before any design, the supplier shall check the applicable rules based on RISL with its customers.
When designing a part and components and their assemblies, the suppliers shall verify the presence of the P(AR), D(FA) or D(FI) substances by checking:

- Its SDS (Safety Data Sheet) if the part is made from mixtures of substances, i.e., non-finished products (ex: paints, glues, resin, soldering mixtures...);
- With its own suppliers.

In case **P(AR) or D(FA) substances** are detected, the field “Controlled application” shall be checked to determine if the use (application) is strictly prohibited, i.e., P(AR) case is still permitted in certain conditions depending on approval from the customer, i.e., D(FA) case.

If a **P(AR) substance** is detected, selected parts, components or assemblies are not compliant with legislation. Consequently, the design shall be changed.

If a **D(FA) substance** is detected, there is a risk of future prohibition or contractual nonconformity. In that case, the possibility of substitution shall be investigated, and substitution shall be made if an alternative exists.

If a **D(FI) substance** with a relevant mass (above 0.1 % w/w) is detected, the information shall be recorded and consulted for legislation and RISL updates.

How to use the RISL during parts and components delivery to customers?

Before any supply, the supplier shall check the applicable rules based on RISL with its customers.
In general, the following rules shall apply:

- The supplier shall commit that no **P(AR) substance** is present in its scope of supply before any delivery.
- The supplier shall declare all **D(FA) substances** present in its scope of supply before freezing the design and be aware that D(FA) could be prohibited.
- If the customer requests, the supplier has to declare **D(FI) substances** with a relevant mass (above 0.1 % w/w) to the customer before delivery.