

Substance compliance requirements for Vaisala parts

Substance compliance requirements concerning mechanical and electronic parts supplied for Vaisala products

Author:	Milla Miettinen	Status:	Accepted
Issue date:	2024-06-04	Revision:	C
Identifier:	PI220903	Pages:	1 (9)

Revision history

Revision	Date/Name	Description of change	Approver
A	2022-09-09/Milla Miettinen	Document created	Maija Grönlund
B	2023-06-07/Milla Miettinen	Title modified, EU POP regulation and CoC requirement added	Maija Grönlund
C	2024-06-04/Milla Miettinen	Transferred to new brand template; UK RoHS and PFAS requirements added; Vaisala CoC template attached and Annex I referenced	Jorma Lammila

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Substance compliance requirements for Vaisala parts

This document provides a description of the substance compliance requirements concerning mechanical and electronic parts supplied for Vaisala products.

1 Purpose and Scope

The purpose of this document is to raise awareness of the supplier’s responsibility to comply with the applicable requirements. The applicable requirements may arise from national, federal, or international regulation or internal decisions by Vaisala ("Vaisala" referring to the entire Vaisala group, including its affiliates).

Mechanical and electronic parts supplied for Vaisala products, including commercially manufactured parts and built-to-spec parts using Vaisala drawings, must comply, at minimum, with the requirements described in this document. This document does not provide an exhaustive description of all the applicable requirements, and it is the supplier’s responsibility to verify the applicability of, and its compliance with, the requirements.

2 Substance Restrictions by Regulatory Frameworks

In the table below, a summary of various regulatory frameworks and related substance restrictions is provided. More detailed information, such as the restriction thresholds and CAS numbers, is provided in the following sub-chapters.

Geographical Scope	Regulatory Framework	Shorthand	Restricted Substances
European Union	Restriction of Hazardous Substances	EU RoHS	<ul style="list-style-type: none">• Lead• Cadmium• Mercury• Hexavalent chromium• Polybrominated biphenyls (PBB)• Polybrominated diphenyl ethers (PBDE)• Bis(2-ethylhexyl) phthalate (DEHP)• Butyl benzyl phthalate (BBP)• Dibutyl phthalate (DBP)• Diisobutyl phthalate (DIBP)
European Union	Registration, Evaluation, Authorisation and Restriction of Chemicals	EU REACH	<ul style="list-style-type: none">• Substances on the Candidate List of Substances of Very High Concern for Authorisation (SVHCs), up-to-date list available on ECHA’s website• Substances restricted under Annex XVII, up-to-date list available on ECHA’s website

European Union	Persistent Organic Pollutants Regulation	EU POPs	<ul style="list-style-type: none">Substances on the list of substances subject to POPs Regulation, up-to-date list available on ECHA's website
United Kingdom	Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012	UK RoHS	<ul style="list-style-type: none">See EU RoHS
United States	Toxic Substances Control Act	US TSCA	<ul style="list-style-type: none">Phenol, isopropylated phosphate (3:1) (PIP (3:1))Decabromodiphenyl ether (DecaBDE)2,4,6-tris(tert-butyl)phenol (2,4,6 TTBP)Hexachlorobutadiene (HCBd)Pentachlorothiophenol (PCTP)

2.1 EU Restriction of Hazardous Substances (RoHS)

The European Union's RoHS Directive (Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment) restricts certain substances in different categories of electrical and electronic equipment (EEE). Vaisala products belong to **category 9, industrial monitoring and control instruments**. Please note that the RoHS Directive includes the original act as well as any subsequent amendments (such as Commission Delegated Directive (EU) 2015/863).

The RoHS Directive restricts the following substances in electrical and electronic equipment:

- Lead (0,1 %)
- Mercury (0,1 %)
- Cadmium (0,01 %)
- Hexavalent chromium (0,1 %)
- Polybrominated biphenyls (PBB) (0,1 %)
- Polybrominated diphenyl ethers (PBDE) (0,1 %)
- Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)
- Butyl benzyl phthalate (BBP) (0,1 %)
- Dibutyl phthalate (DBP) (0,1 %)
- Diisobutyl phthalate (DIBP) (0,1 %)

These substances must not be present in parts supplied for Vaisala products in concentrations above the thresholds (value by weight in homogeneous materials) specified in the Directive, unless the application is exempted from the restriction by a valid RoHS exemption in the same category of EEE. Should the application benefit from an exemption, the supplier must communicate this to Vaisala (see section 3, Providing substance compliance information to Vaisala).

2.2 EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

REACH (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) encompasses several rules, obligations and requirements regarding substances and mixtures. The parts of REACH relevant to Vaisala parts are Authorisation and Restriction.

2.2.1 Candidate List of Substances of Very High Concern (SVHCs)

The Candidate List of Substances of Very High Concern for Authorisation includes substances that meet the criteria for authorisation under REACH Annex XIV. The list is updated twice a year with new substances, and substances will periodically be moved from the Candidate list to the Authorisation list.

An up-to-date list of Substances of Very High Concern can be found on the European Chemical Agency's website: <https://echa.europa.eu/candidate-list-table>

Candidate List substances may be present in parts and materials supplied for Vaisala products. Whenever they are present in concentrations above 0,1 % weight by weight on article level, the supplier must communicate this to Vaisala according to REACH Article 33(1) (see section 3, Providing substance compliance information to Vaisala).

Suppliers are strongly advised to phase out Candidate List substances from parts supplied to Vaisala to minimize future risks.

2.2.2 Annex XVII

REACH Annex XVII restricts the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles on the EU market. Conditions of restriction vary by substance and therefore restrictions are application-specific.

An up-to-date list of substances restricted under Annex XVII can be found on European Chemical Agency's website: <https://echa.europa.eu/fi/substances-restricted-under-reach>

Parts supplied for Vaisala products must not contain substances restricted under Annex XVII in concentrations above those specified in substance-specific conditions of restriction whenever those conditions concern the part itself. For the sake of clarity, should the conditions of restriction apply to the end product manufactured by Vaisala but not the part itself, Vaisala is responsible for identifying the restriction. However, to meet this requirement, Vaisala needs to have up-to-date information regarding materials restricted under Annex XVII used in the parts supplied by the supplier (see section 3, Providing substance compliance information to Vaisala).

2.3 EU Persistent Organic Pollutants Regulation (POPs)

The European Union's POPs Regulation (Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants) implements the international treaties of Stockholm Convention and the Aarhus Protocol on persistent organic pollutants (POPs). Substances subject to the EU POPs Regulation are prohibited or severely restricted, including manufacturing, placing on the market and use in articles.

And up-to-date list of substances subject to the POPs Regulation can be found on European Chemical Agency's website: <https://echa.europa.eu/list-of-substances-subject-to-pops-regulation>

These substances must not be present in parts supplied for Vaisala products in concentrations above the thresholds specified in the Regulation, unless the part benefits from a derogation. Should the application benefit from a

derogation, the supplier must communicate this to Vaisala (see section 3, Providing substance compliance information to Vaisala).

2.4 UK Restriction of Hazardous Substances (RoHS)

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 of the United Kingdom restricts certain substances in different categories of electrical and electronic equipment (EEE). The UK RoHS largely follows the restrictions and scope of the EU RoHS Directive (see 2.1 for the list of substances).

Exemptions under the UK RoHS are independent of exemptions under the EU RoHS. The current exemptions in tables 1 and 2 of the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (the RoHS regulations) can be found on the UK legislation website:
<https://www.legislation.gov.uk/ukxi/2020/1647/schedule/2/made>

For the time being, it is sufficient that the supplier communicates any EU RoHS exemptions that the parts supplied to Vaisala benefit from (see section 3, Providing substance compliance information to Vaisala).

2.5 US Toxic Substances Control Act (TSCA)

The Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under Section 6(h) of the Toxic Substances Control Act (Federal Regulations of the United States, Title 40 – Protection of Environment, Part 751) currently restricts or prohibits the use of five persistent, bioaccumulative and toxic (PBT) chemicals in products sold within the United States market. The prohibitions and restrictions concern articles in addition to chemicals and mixtures.

The following chemicals are currently regulated with the following dates and concentrations:

- **Phenol, isopropylated phosphate (3:1)** (PIP (3:1), prohibited as of Oct 31, 2024
- **Decabromodiphenyl ether** (DecaBDE), prohibited as of Jan 6, 2022
- **2,4,6-tris(tert-butyl)phenol** (2,4,6 TTBP), 0.3 % at product level as of Jan 6, 2026
 - only applies to raw TTBP and oil or lubricant additives
- **Hexachlorobutadiene** (HCBd), prohibited as of Mar 8, 2021
- **Pentachlorothiophenol** (PCTP), 1 % at product level as of Jan 6, 2022

These substances must not be present in parts supplied for Vaisala products in concentrations at or above the thresholds specified in the regulation.

2.6 PFAS requirements

Per- and polyfluoroalkyl substances (PFAS) are regulated or planned to be regulated in many parts of the world, including, but not limited to, the EU, the United States on a federal level, and individual states of the US. Some of these regulations are listed below.

- United States: Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances Under Section 8(a)(7) of the Toxic Substances Control Act (Federal Regulations of the United States, Title 40 – Protection of Environment, Part 705)
- Maine (USA): Restriction of Products Containing Perfluoroalkyl and Polyfluoroalkyl (PFAS) Substances, House Paper 1113, Legislative Document 1503 Enacted, 2021 *and amendments*

- EU: Restriction proposal for Per- and polyfluoroalkyl substances (PFASs) under REACH Annex XVII

To prepare for restrictions and reporting requirements, Vaisala needs to have information on PFAS contained in parts supplied to us (see section 3, Providing substance compliance information to Vaisala). For the purposes of this data collection, PFAS are defined as a class of organic chemicals containing at least one fully fluorinated carbon atom. For the time being, fluoropolymers and fluoroelastomers are included in the scope.

3 Providing substance compliance information to Vaisala

When applicable, use of RoHS exemptions and EU POP derogations, presence of REACH SVHCs, information regarding materials restricted under Annex XVII of REACH, and presence of PFAS must be communicated to Vaisala.

The communication may take place in electronic form (Annex 1 to this document), or the information may be presented on the supplier data sheet. The information must also be provided free of charge upon request by Vaisala or a third-party service provider contracted by Vaisala to collect such information, including compliance with applicable substance restrictions not limited to RoHS exemptions or REACH SVHCs.

Suppliers are required to provide Vaisala with signed and dated Certificates of Compliance (CoC) specifying the regulations against which compliance is claimed and the parts covered by the CoC. Appendix 1 to this document contains a Certificate of Compliance template that suppliers may use, if not providing their own.

Notice

The laws and regulations referenced in this document are subject to change. The requirements concerning parts supplied for Vaisala products do not depend on the updating cycle of this document but are the supplier's responsibility to actively follow-up on, whenever they are based on such laws and regulations. Supplied parts must therefore fulfill all the requirements set forth by the laws and regulations valid at the time of purchase.

Certificate of Compliance

Vaisala Oyj and its affiliates ("Vaisala") are committed to meeting all safety protocols and substance compliance requirements arising from national, federal, and international regulations, including the regulations listed in the document *Compliance requirements for Vaisala parts* ("Compliance Requirements"). It is essential that you as a supplier of products or components to Vaisala ("Supplier") also meet these compliance requirements and provide substance information to Vaisala when necessary, and fully indemnify Vaisala for any instance that such requirements are violated.

The Supplier hereby certifies that the Supplier is compliant and shall, to the best of its abilities, ensure future compliance with the requirements laid out in the Compliance Requirements regarding all products and components listed in Appendix 1 and any subsequent changes and additions to Supplier's scope of deliveries to Vaisala.

To the extent Supplier violates the Compliance Requirements, whether or not Supplier is aware of such violations, Supplier shall hold harmless, defend and indemnify Vaisala and its respective directors, officers, members, managers, employees, consultants, contractors, and agents from and against any and all third-party claims, demands, suits, actions, or proceedings (and resulting costs, attorney's fees, expenses and liabilities) which arise from, or are caused by, the discovery of any prohibited substances or amounts of substances in any products Supplier sells or otherwise provides to Vaisala.

These terms will be governed by and construed in accordance with the laws of Finland. It is expressly agreed that the application of United Nations Convention on Contracts for the International Sale of Goods (CISG) will not apply to these terms or to any dispute arising therefrom.

AGREED:

Supplier: _____

(Company's Full Corporate Entity Name)

By: _____

Name: _____

Date: _____