



IE Directive

Material Compliance

Guideline for ensuring material compliance requirements for measuring and calibration equipment

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1 INTRODUCTION

The purpose of the IE Directive - Material Compliance - is to ensure the safe handling of substances and products that may be used or incorporated in test and calibration equipment in the European Union.

This guideline describes the requirements of Image Engineering GmbH & Co. KG (IE Customer) regarding all known prohibited, regulated and declarable substances in their current form.

The material compliance requirements are equal to the other product requirements.

The Material Compliance Guideline is a compilation of the legal requirements. Suppose any changes to the law are not yet shown in this guideline. In that case, this does not release the supplier from the obligation to consider these law changes and comply with the current, applicable legal requirements. The supplier is obliged to obtain the respective current guidelines, laws and standards himself.

Products and raw materials of unknown origin and/or composition, or raw materials of which no sufficient material data are available, must not be used.

In individual cases, the technical data sheets of all raw materials and auxiliary materials used shall be submitted to the customer, except for end consumers, for initial sampling upon request. The customer reserves the right to conduct tests and laboratory examinations on materials in individual cases.

The supplier is obliged to provide the material information required to check compliance with the legal requirements and these guidelines free of charge.

IE makes the policy available via its website.

The supplier is obliged to regularly check whether the guideline is available in an updated form. The amendment of the guideline replaces the previous version and is valid with immediate effect. IE shall inform those internally about new versions or revisions of the guideline. IE shall not notify the supplier about the amendment of the guideline.



2 TERMS AND ABBREVIATIONS

Fabric:

A chemical element and its compounds in natural form or obtained by a manufacturing process, including additives necessary to maintain its stability and impurities resulting from the process used, but excluding solvents which can be separated from the substance without affecting its stability or changing its composition (cf. REACH Art. 3(1)).

Examples of chemical compounds

Organic: water, formaldehyde, ethanol

Metallic: iron, copper, tin

Mineral: iron sulfide, sodium chloride, silicic acid

Preparation:

Mixtures, blends or solutions of two or more substances (mixture and preparation are synonymous).

Examples of preparations:

Batch: Sand

Mixture: Air

Solution: Octane in petrol

Homogeneous material:

Indicates a material of uniform composition throughout or a material consisting of different materials which cannot be broken down or separated into individual materials by mechanical processes such as unscrewing, cutting, crushing, grinding and sanding (cf. RoHS Art. 3 Para. 20). Examples of homogeneous materials include individual types of plastics, ceramics, glasses, metals, alloys, synthetic resins and coatings.

Added intentionally:

Generally known as the intentional use of a substance contained in an article to produce a particular property, appearance or quality.

Battery or accumulator:

Indicates a source of electrical energy consisting of one or more (non-rechargeable) primary cells or one or more (rechargeable) secondary cells obtained by direct conversion of chemical energy.

Packaging:

Products made of any substance to contain for protection, handling, delivery and presentation of goods may range from raw material to processed products and are passed on by the producer to the user or consumer. All "disposable" articles used for the same purpose are also to be considered as packaging (cf. EU Packaging Directive Art. 3 Para. 1)

Packaging components:

These are parts of the packaging that can be separated by hand or by simple mechanical operations. Additional elements directly attached or fastened to a product and fulfilling a packaging function are considered packaging unless they are an integral part of the product.

Prohibited substances:



Prohibited substances must not be contained in articles, components, materials, preparations and auxiliary and operating materials above the limit values specified in this document. These substances may only be present as naturally occurring impurities; they may not be added intentionally. Impurities with these substances shall be qualitatively indicated.

Declarable substances:

Substances classified as declarable are undesirable in some applications and must be declared above the specified limits. The listed substances must be identified for each article, component, material, substance preparation, auxiliary or operating material, and content limits are defined in the document for the individual substances. Below these limits, the declaration is not required.

Application:

The application indicates that the limit value of the substance refers to the material or part in which the substance is contained to achieve a desired functionality.

Product:

A product is an object which, during manufacture, is given a specific shape, surface or design which determines its function to a greater extent than its chemical composition.

Application deadline (Latest application date):

According to the REACH Regulation, an application for authorization must be submitted by this date (at least 18 months before the expiry date) so that the substance can continue to be used (Deadline).

Information on the application for admission and the formal procedure of an application for admission can be found at:

<https://echa.europa.eu/applications-for-authorisation-consultation>

Expiry date (Sunset date):

After this date, the placing on the market and using a substance listed in Annex XIV of REACH is prohibited unless authorization has been granted.

CAS number:

The CAS number (also CAS Registry Number, CAS = Chemical Abstracts Service) is an international designation standard for chemical substances. A unique CAS number for each chemical substance (including biosequences, alloys and polymers) is registered in the CAS database.



3 IE LIST OF REGULATED SUBSTANCES

3.1 SUBSTANCE REGULATIONS AND BANS - RELEVANT FOR ALL PRODUCTS

The substance-related requirements described under point 3.1 apply to all articles that

- are installed in test and calibration equipment under the responsibility of the manufacturer
- are intended for installation in test and calibration equipment.

3.1.1 REGULATION (EC) No 1907/2006 REACH - ANNEX XIV - LIST OF SUBSTANCES SUBJECT TO AUTHORIZATION

The inclusion of a substance from the list of substances of very high concern in Annex XIV of the REACH Regulation leads to an authorization requirement for this substance at the end of the procedure. After a transitional period, the substance may only be used with authorization, or its use is banned.

The terms application deadline and expiry date are explained under point 2, Definitions and abbreviations.

You can access the current Annex XIV of the REACH Regulation under the following link <https://echa.europa.eu/de/authorisation-list>

3.1.2 REGULATION (EC) No 1907/2006 REACH - ANNEX XVII - LIST OF RESTRICTED SUBSTANCES

Annex XVII of the REACH Regulation regulates or bans precisely defined substances in individual applications.

Under the following link, you can access the current Annex XVII of the REACH Regulation:

<https://echa.europa.eu/de/substances-restricted-under-reach>

3.1.3 CHEMICALS PROHIBITION ORDINANCE - CHEMVERBOTS V

The Ordinance on Prohibitions and Restrictions on the Marketing of Hazardous Substances, Preparations, and Products under the Chemicals Act is a German law that prescribes specific national requirements in addition to the REACH Regulation. As REACH is a regulation that applies directly in the EU member states, an amendment to the ChemVerbotsV was passed in 2016 that combines the REACH and CLP regulations requirements with German chemicals law. The national requirements for the following substances and substance groups were also defined:

**Table 1: ChemVerbotsV Substance and substance groups**

Substances/mixtures
Formaldehyde
Dioxins and furans
Pentachlorophenol
Biopersistent fibers

The specific requirements and the listed exceptions can be found in the text of the law.

The requirements of the new Chemicals Prohibition Ordinance came into force on 01.01.2019.

http://www.gesetze-im-internet.de/chemverbotsv_2017/index.html

3.1.4 REGULATION (EU) 2019/1021 - PERSISTENT ORGANIC POLLUTANTS (POPs)

This EU Regulation implements, among others, the Stockholm Convention on Persistent Organic Pollutants. The Stockholm Convention, also known as the POP Convention, is an agreement on prohibition and restriction measures for certain persistent organic pollutants that are binding under international law. Thus, the Convention bans or restricts the production, use and trade of 22 hazardous chemicals.

Further information on the Stockholm Convention can be found on the <http://chm.pops.int/> official website at the following link:

<http://chm.pops.int/>

3.1.5 PACKAGING GUIDELINE

DIRECTIVE 94/62/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 1994 on packaging and packaging waste limits the concentration of heavy metals in packaging.

Table 2: Substance restriction packaging

Pure substances and groups of substances	Maximum concentration in Packaging or Packaging components in weight ppm
Lead, cadmium, mercury and chromium VI	100*

*cumulative



3.1.6 PACKAGING ACT - VERPACKG

The Packaging Act is intended to ensure that those who bring packaging into circulation for the first time, which private end users end up with as waste, contribute fully to the costs of collection, sorting and recycling.

This act means that the new packaging law affects not only manufacturers but also (online) retailers, online shops and importers.

You can find the full text of the law under the following link:

<https://www.gesetze-im-internet.de/verpackg/>

3.2 SUBSTANCE REGULATIONS AND BANS - RELEVANT FOR PRODUCTS IN DIFFERENT AREAS OF APPLICATION

In contrast to the substance regulations in section 3.1, the supplier must check here whether his products fall within the scope of the individual requirement. This requirement depends on the place of installation and use of the supplied product in test and calibration facilities. If it is not possible for the supplier to clarify this matter independently, he must consult his customer.

3.2.1 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 (RoHS Directive) came into force on 2 January 2013.

The list of exemptions for substance bans can be found in Annex III of Directive 2011/65/EU.

The RoHS substance regulations refer to the maximum concentrations in the homogeneous material of each article.

Table 3: Substance regulations of the RoHS Directive according to 2011/65/EU Annex II

Substance groups	Maximum concentration in the homogeneous Material in percent
Cadmium and cadmium compounds	0,01%
Hexavalent chromium (Cr6+) and Cr6+ compounds	0,10%
Lead and lead compounds	
Mercury and mercury compounds	
Polybrominated diphenyl ethers (PBDE)	
Polybrominated biphenyls (PBB)	
Di(2-ethylhexyl) phthalate (DEHP)	
Butyl benzyl phthalate (BBP)	
Dibutyl phthalate (DBP)	
Diisobutyl phthalate (DIBP)	



3.2.2 EU TIMBER REGULATION

The EU Regulation prohibits the import of illegal timber and illegal timber products in Art. 4 para. 1. Special duties of care are imposed on those who bring timber into internal traffic within the EU for the first time. In Germany, the "Act against Trade in Illegally Logged Timber" puts the EU Regulation into concrete terms.

All materials and components made of wood or wood components must comply with the requirements of the EU Timber Regulation.

Examples: Packaging materials, wooden boxes

3.2.3 BIOCIDAL PRODUCTS REGULATION (EU) No 528/2012

On 1 September 2013, the Biocidal Products Regulation (BPR, EU Regulation No. 528/2012) on the supply and use of biocidal products on the European market entered into force. With this regulation, the authorization of biocides is uniformly regulated in the European Union and takes place in a staged procedure.

Every supplier of IE is obliged to comply with the specifications and obligations for

- Biocidal products
- Treated goods

Fully comply if its product falls within the scope of the Regulation.

All materials and components treated with biocidal substances must comply with the EU Biocidal Products Regulation requirements.

Examples: Wood treatment, cleaning agents

3.3 PRODUCTION AUXILIARIES AND OPERATING MATERIALS

3.3.1 SAFETY DATA SHEETS (SDS)

The safety data sheet is the central element of communication in the supply chain for hazardous substances and mixtures, and it provides crucial information on the following features:

- Identity of the product
- Hazards encountered
- Safe handling
- Prevention measures
- Measures to be taken in the event of danger

The requirements for the content and format of the safety data sheet are laid down in Article 31 and Annex II of REACH Regulation (EC) No 1907/2006.



The substance/mixture supplier is responsible for ensuring the safety data sheet is technically correct and completed in full.

The safety data sheet shall be made available to IE free of charge on paper, in electronic form or as a download option at the latest on the day of the 1st delivery.

Suppliers shall update the SDS without delay (Art. 31 (9)) if:

- New information is available that may have an impact on risk management measures
- An authorization has been granted or refused
- A restriction has been imposed

The corrected version must be made available to the customer if they have been supplied within the last 12 months.

3.4 SUBSTANCES SUBJECT TO DECLARATION

3.4.1 SVHC CANDIDATE LIST

The current version of the official SVHC candidate list, according to REACH (Regulation 1907/2006/EC), can be downloaded at any time from the address:

<https://echa.europa.eu/de/candidate-list-table>

According to Article 33 of the REACH Regulation, each supplier is obliged to do the following:

(1) Any supplier of an article containing a substance that meets the criteria of Article 57 and is identified under Article 59(1) in a concentration greater than 0,1 % by mass (w/w) shall provide the recipient of the article with the information available to him. This information is sufficient for the safe use of the article but shall provide at least the name of the substance concerned.

Ingredients of very high concern (SVHC candidate list) in

- Components
- Spare parts
- Accessories
- Packaging

Insofar as the delivered articles contain substances of very high concern in a proportion of more than 0.1% by weight, published in the so-called candidate list under Art. 59 para. 1 of Regulation 1907/2006/EC, the supplier is obliged to provide, upon delivery, all information under Art. 33 para. 1 of Regulation 1907/2006/EC without being requested to do so. This step also applies if such a substance is only included in the candidate list during the ongoing supply relationship.

Private consumers shall be provided with this information free of charge upon request within 45 days.



According to the decision of the European Court of Justice, the concept "once an article, always an article" applies. As soon as an article exceeds the concentration limit of 0.1%, the presence of this SVHC candidate substance has to be communicated.

Since 2021, it has been mandatory for European companies, in addition to Article 33 (1) and (2), to communicate and register articles with SVHC candidates in the SCIP database of the European Chemicals Agency (ECHA). We recommend that each company communicate the SCIP IDs obtained for the registered articles with their European customers.

3.5 FURTHER REQUIREMENTS

3.5.1 INDOOR EMISSIONS (VOC)

Suppliers are expected to provide the following

- Materials
- Components
- Accessories

Pay special attention to possible emissions with volatile organic compounds (VOC). Volatile organic compounds from hydrocarbons can be formed in natural products such as wood or plastics through raw materials and manufacturing processes.

If such volatile organic substances that could contribute to indoor emissions are present in the article, the subsequent customer in the supply chain must be informed.

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5 Change index

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