BS EN 50581:2012

BSI Standards Publication

Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee GEL/111, Electrotechnical environment committee.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 50581

September 2012

ICS 29.020; 31.020

English version

Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Documentation technique pour l'évaluation des produits électriques et électroniques par rapport à la restriction des substances dangereuses

Technische Dokumentation zur Beurteilung von Elektro- und Elektronikgeräten hinsichtlich der Beschränkung gefährlicher Stoffe

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Management Centre: Avenue Marnix 17, B - 1000 Brussels

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Contents

Foreword

This document (EN 50581:2012) has been prepared by CLC/TC 111X "Environment".

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2013-07-16
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2015-07-16

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 2011/65/EU.

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Introduction

Certain substances contained in electrical and electronic products are restricted by legislation and/or customer specifications. Manufacturers of final products therefore need to be able to demonstrate that their products meet the applicable substance restrictions.

For those restrictions that apply at the “homogeneous material" level, it is impractical for manufacturers of complex products to undertake their own testing of all materials contained in the final assembled product. Instead, manufacturers work with their suppliers to manage compliance and compile technical documentation as evidence of compliance. This approach is well recognised by both industry and enforcement authorities.

The aim of this European Standard is to specify the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions. In this way, this European Standard supports 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).

This European Standard can also find an application in demonstrating conformity to other substance regulations worldwide.

1 Scope

This European Standard specifies the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions.

The documentation of the manufacturer's management system is outside the scope of this European Standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 62321:2009, *Electrotechnical products — Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers) (IEC 62321:2008)*

NOTE EN 62321 will be replaced by a series of standards designated EN 62321-x.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
restricted substance
substance which is limited in its use in a product, part or material

3.2
manufacturer
natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark

[SOURCE: Regulation (EC) N° 765/2008 or Decision N° 768/2008/EC]

Note 1 to entry: In certain circumstances, an importer or distributor is considered a manufacturer for the purposes of Directive 2011/65/EU.

3.3
supplier
organisation that provides the manufacturer with materials, parts and/or sub-assemblies

4 Technical documentation

4.1 Overview

The manufacturer shall compile technical documentation to demonstrate that electrical and electronic products comply with substance restrictions (see 4.2 and 4.3).

4.2 Content of the technical documentation

The technical documentation shall include at least the following elements:

– a general description of the product;

NOTE 1 Directive 2011/65/EU specifies 11 product categories. The product category is one of the factors that determines which exemptions apply.

– documents for materials, parts, and/or sub-assemblies (see 4.3);

– information showing the relationship between the technical documents identified in 4.3 and the corresponding materials, parts and/or sub-assemblies in the product;

– list of harmonized standards and/or other technical specifications that have been used to establish the technical documents identified in 4.3, or to which such documents refer.

NOTE 2 Annex A describes the relationship between Article 7(b) of Directive 2011/65/EU, Module A of Decision 768/2008/EC, this European Standard, and the technical documentation.

4.3 Information on materials, parts, and/or sub-assemblies

4.3.1 Tasks to be undertaken by the manufacturer

The manufacturer shall undertake the following four tasks:

– determine the information needed (see 4.3.2);

– collect the information (see 4.3.3);

– evaluate the information with regard to its quality and trustworthiness and decide whether to include it in the technical documentation (see 4.3.4);

– ensure that the technical documentation remains valid (see 4.3.5).

Figure 1 (informative) shows the process to create the technical documentation:

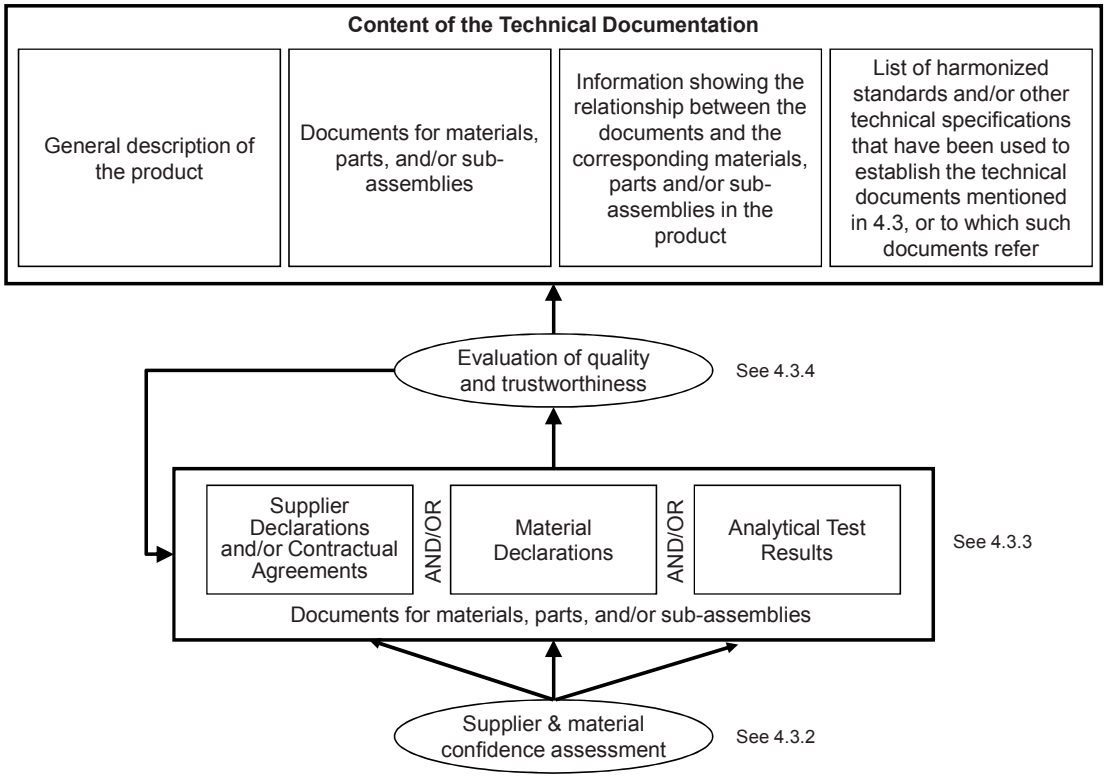

Figure 1 — Schematic representation of process to create the technical documentation

4.3.2 Determine the information needed

The types of technical documents (see 4.3.3) that are required for materials, parts and/or sub-assemblies shall be based on the manufacturer's assessment of:

a) the probability of restricted substances being present, in materials, parts or sub-assemblies, and

b) the trustworthiness of the supplier.

Materials that are added during the production process (such as solder, paint, adhesives) shall also be considered as part of the assessment.

When undertaking the assessment described in point a), the manufacturer may apply technical judgement, as some substances are unlikely to be contained in certain materials (e.g. organic substances in metals). Such technical judgement could be based on technical information available via the electrical/electronic industry, or a literature investigation of the materials/parts used in electrical/electronic products.

NOTE 1 Additional information that can be used when undertaking the assessment described in points (a) and (b) includes:

- material types typically used in the part or sub-assembly;
- historical likelihood of restricted substances being present in each material type;
- historical experience with the supplier organization;
- results of previous supplier inspections or audits.

NOTE 2 The assessment and its associated procedures can form part of a quality management system or equivalent.

4.3.3 Collecting information

As a result of the manufacturer's assessment, the following documents on materials, parts, and/or sub-assemblies shall be collected:

a) Supplier declarations and/or contractual agreements, such as:
   - Supplier declarations, confirming that the restricted substance content of the material, part, or sub-assembly is within the permitted levels and identifying any exemptions that have been applied;
   - Signed contracts confirming that the manufacturer's specification for the maximum content of restricted substances in a material, part, or sub-assembly is fulfilled.

   Such declarations or agreements shall cover a specific material, part and/or sub-assembly, or a specific range of materials, parts and/or sub-assemblies.

   and/or

b) Material Declarations:
   - Material declarations providing information on specific substance content and identifying any exemptions that have been applied.

     NOTE 1 The use of standards for such declarations helps ensure consistent and cost-effective flow of information throughout the supply chain. EN 62474 "Material declaration for products of and for the electrotechnical industry" describes the procedure, content, and form relating to material declaration. Other specifications for material declarations are also used in industry today.

   and/or

c) Analytical test results:
   - Analytical test results using the methods described or referenced in EN 62321.

     NOTE 2 EN 62321 will be replaced by a series of standards designated EN 62321-x.

4.3.4 Evaluation of information

The manufacturer shall establish procedures that shall be used to evaluate the documents described in 4.3.3 in order to determine their quality and trustworthiness.

NOTE 1 IEC/TR 62476 provides a framework for the use of internationally accepted standards, tools and practices to evaluate electrical and electronic products with respect to restricted substances.

The manufacturer shall evaluate, in accordance with these procedures, the source and content of each document received in order to determine whether or not the material, part, or sub-assembly meets the specified substance restrictions.

NOTE 2 The substance restrictions specified in Directive 2011/65/EU apply at the homogeneous material level.

This evaluation will enable the manufacturer to decide whether the documents provide sufficient evidence of compliance to justify their inclusion in the technical documentation. If a particular document is:

- considered to be of sufficient quality and trustworthiness, then it shall be included in the technical documentation;
- not considered to be of sufficient quality or trustworthiness, then the manufacturer shall determine what further actions are necessary – possible actions include requesting additional information from the supplier or undertaking his own substance analysis.

4.3.5 Review of the technical documentation

The manufacturer shall:

- perform a periodic review of the documents contained in the technical documentation to ensure that they are still valid;
- ensure that the technical documentation reflects any changes to materials, parts or sub-assemblies in accordance with 4.3.3.

NOTE Directive 2011/65/EU requires that “manufacturers ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account”.

Annex A
(informative)

Relationship between Directive 2011/65/EU and the technical documentation

Figure A.1 shows the relationship between Article 7(b) of Directive 2011/65/EU, Module A of Decision 768/2008/EC, this European Standard, and the technical documentation:

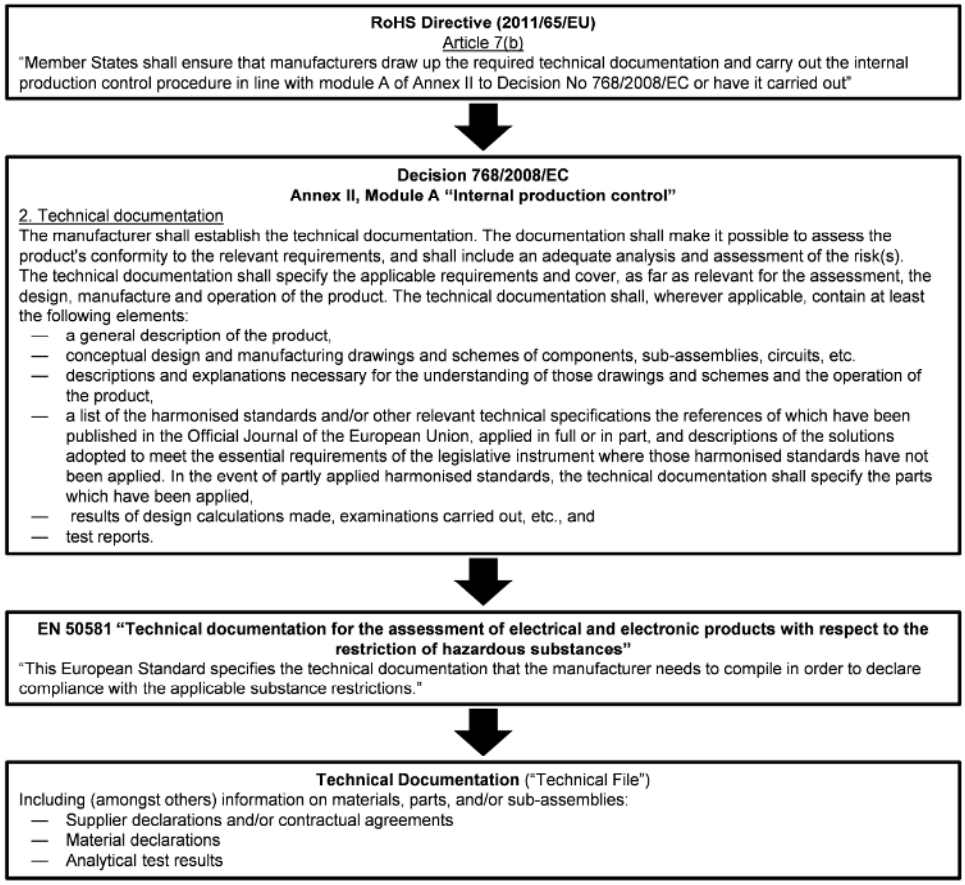

Figure A.1 — Relationship between Directive 2011/65/EU and the technical documentation covered by this standard

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Article 7 of Directive 2011/65/EU.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other Directives may be applicable to the products falling within the scope of this standard.

Bibliography

EN 62474:2012, *Material declaration for products of and for the electrotechnical industry (IEC 62474:2012)*

EN 62430:2009, *Environmentally conscious design for electrical and electronic products (IEC 62430:2009)*

IEC/TR 62476:2010, *Guidance for evaluation of products with respect to substance use restrictions in electrical and electronic products*

IEC/PAS 62596:2009, *Electrotechnical products — Determination of restricted substances — Sampling procedure — Guidelines*

EN ISO 9001, *Quality systems — Requirements (ISO 9001)*

EN ISO 14001, *Environmental management systems — Requirements with guidance for use (ISO 14001)*

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

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

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