

TECHNICAL REPORT

**Guidance for evaluation of products with respect to substance-use restrictions
in electrical and electronic products**

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE

R

ICS 13.020; 43.040.10

ISBN 978-2-88910-737-7

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**GUIDANCE FOR EVALUATION OF PRODUCTS
WITH RESPECT TO SUBSTANCE-USE RESTRICTIONS
IN ELECTRICAL AND ELECTRONIC PRODUCTS**

FOREWORD

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IEC/TR 62476, which is a technical report, has been prepared by subcommittee IEC technical committee 111: Environmental standardization for electrical and electronic products and systems.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
111/158/DTR	111/172/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

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INTRODUCTION

The restriction of substances in electrical and electronic products is a growing focus of regulation and customer specifications. Producers, therefore, have a greater need to establish processes to meet the substance restrictions requirements in such electrical and electronic products. Due to the complexity of the electrical and electronic industry supply chain, a flexible framework is necessary for the many different types of electrical and electronic product parts and equipment producers.

Criteria for the restriction of substances may differ from one piece of legislation to another and from one customer's requirement to another.

Generally, "presumption of conformity" is assumed. However, in the event of additional evidence being required, producers make relevant documentation available to interested parties. This documentation can be based on physical testing using analytical techniques. However, it is difficult to perform comprehensive analytical testing on complex products and therefore several different evaluation methods, such as information from the supply chain, may be needed.

The aim of this technical report is to provide guidance on the application and limitation of evaluation methods, and associated technical documentation, based on International Standards and industry practices.

The application of appropriate evaluation methods is defined by a producer for a specific product. This technical report provides the basis for a restricted substance control framework.

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GUIDANCE FOR EVALUATION OF PRODUCTS WITH RESPECT TO SUBSTANCE-USE RESTRICTIONS IN ELECTRICAL AND ELECTRONIC PRODUCTS

1 Scope

IEC/TR, which is a technical report, provides a framework for the use of internationally accepted standards, tools and practices to evaluate electrical and electronic products with respect to restricted substances. This technical report can also be applied to declarable substances which are not restricted in electrical and electronic products.

This technical report provides guidance on how technical documentation and relevant evaluation and control methods should be selected and applied for restricted or declarable substances of any producer's product.

It is not intended for setting a new management scheme or for certification purposes. Evaluation and control methods for substances in products can be integrated into an existing management system, where available.

2 Normative references

There are no normative references. Informative references are noted in the bibliography.

NOTE This clause is included so as to respect IEC clause numbering.

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 by regulation or customer contractual requirements

3.2

declarable substance

substance to be declared in a product by regulation or customer contractual requirements

3.3

producer

organization that receives materials, parts and sub-assemblies from suppliers and provides products to customers

NOTE 1 In this technical report the producer has the responsibility to evaluate the product with respect to restricted substance requirements.

NOTE 2 This technical report is written from the perspective of the producer within the supply chain. When the producer provides a product further down in the supply chain his role changes to supplier.

3.4

supplier

organization up-stream to the producer that provides it with materials, parts and/or sub-assemblies

3.5**customer**

organization or person that receives a product

(ISO 9000:2005, 3.3.5, modified)

3.6**restricted substance controls****RSC**

framework of procedures for the control by a producer of restricted substances in its products

3.7**technical documentation**

documents with product-related data and information that are used and retained to demonstrate compliance

NOTE This information could relate to the structure and composition of the product, e.g. test reports or other data describing the materials or product parts used; or it could relate to management systems, e.g. relating to the control of processes used to make the component or product.

3.8**producer self-declaration**

first-party declaration confirming evaluation of product with respect to restricted substance requirements

3.9**product category**

group of technologically or functionally similar products where environmental aspects can reasonably be expected to be similar

(IEC 62430:2009, 3.15)

4 Framework for evaluation of product

It may be necessary for an organization to demonstrate compliance with regulations and market requirements through self-declaration or contractual agreements established along the supply chain. The evaluation of a product may rely on a series of appropriate methods, strategies or processes, for material, parts and/or sub-assemblies of any electrical or electronic product. Multiple methods are generally required, given that electrical and electronic products often contain many materials, parts and/or sub-assemblies with different levels of complexity. Therefore, a multi-level approach for the control of restricted substances in products is beneficial.

The framework covers all design, manufacturing and other operational functions (e.g. procurement) to evaluate the product for restricted substances.

The producer shall define and execute restricted substance controls (RSC) for the operations related to its product category under consideration and ensure the execution of adequate RSC by its suppliers. When evaluating a product, the producer shall have a level of technical documentation that demonstrates effective RSC.

Specific substance restrictions in electrical and electronic products can be required by legislation or customer specifications. The producer should consider relevant sources for substance restrictions.

The RSC should cover, at a minimum, the following elements:

- Restricted substances and evaluation criteria. The product planning and design should indicate product category technologies, structures, product materials, parts and sub-assemblies sourcing and related design process rules.
- Identification of source(s) of information. Depending on the complexity of materials, parts or sub-assemblies in a particular product or product category, one or any combination of the three sources of information (not in any priority order) described below can be used:
 - supplier information;
 - analytical testing;
 - manufacturing and assembling operations, including incoming supply, process and delivery control;
- Evaluation of information.

The producer has responsibility for producing the RSC procedures. This means that the procedures are established, documented and implemented. A procedure for review and continual improvement of restricted substance controls should be established.

NOTE These internally documented procedures could be considered “company confidential” and would not necessarily be shared openly within the supply chain.

Figure 1 illustrates the framework for product evaluation as described above. Applicable IEC TC 111 environment committee standards are referenced in the figure below. See cited clauses for more details.

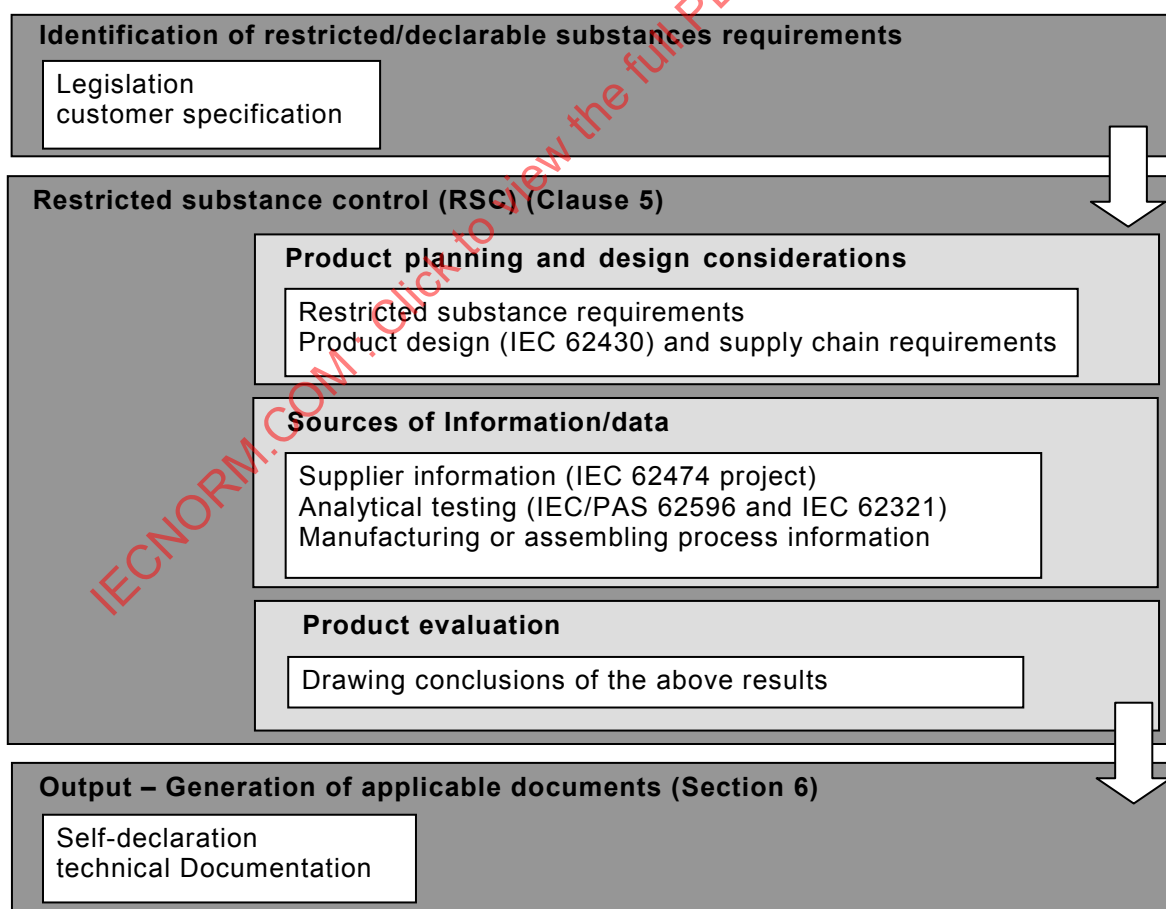


Figure 1 – Framework for evaluation of product

Each producer in the supply chain is responsible for defining his own evaluation methods for each product or product category. The identification of products included in a product category is the responsibility of the producer based on his knowledge of the product line.

RSC is specific to a producer. It may be part of an established quality management system (e.g. ISO 9001) or environmental management system (e.g. ISO 14001) or equivalent management system. It may also be an independent set of documented procedures and their records. A producer relying on outsourced manufacturing needs to ensure that their outsourced manufacturing operations also have effective RSC. Annex A provides examples of RSC requirements in relation to internationally recognized management systems.

The application of evaluation strategies and methods can be unique for every product, but such strategies should be based on the producer's policy, product planning and design and technical documentation. Therefore, the selection or definition of evaluation methods for product materials, parts and/or sub-assemblies should be based on the producer's experience or technical judgment of the likelihood that a restricted substance may be present in either the supply chain or in internal product operations.

Finally, in order to declare that the requirements are met, the producer can provide a "producer self-declaration". If further information is needed, technical documentation can be provided.

5 Restricted substance controls (RSC) considerations

5.1 Product planning and design considerations

The producer top management should ensure that a documented strategy on the control of restricted substances is defined and appropriate for the purpose of the organization. A producer's RSC strategy may be detailed and targeted towards specific product lines or specific environmental regulations, or more general and broader to cover multiple product lines and operations in multiple geographical areas covering multiple environmental regulations, as appropriate to the organization.

As a first step, it is important to develop a list of restricted substances. Documented evaluation methods for different types of materials based on common knowledge or expert competence should be in place for the producer and its suppliers. There should be evidence that procedures are being followed and that materials declarations or other types of technical documentation have been assessed to confirm completeness and accuracy.

A framework for evaluation of a product may lever an environmentally conscious design (ECD) process such as defined by IEC 62430 and as it relates to substance use restrictions. For example, the IEC 62430 standard specifies that the ECD process includes defined steps such as:

- a) analysis of the regulatory and stakeholders' environmental requirements;
- b) identification and evaluation of environmental aspects and corresponding impacts;
- c) product planning, design and development;
- d) review and continual improvement;
- e) sharing ECD information in the supply chain.

At the product planning and design stage, the following information should be available:

- restricted substance requirements (regulatory, customer or other requirements);
- those aspects that have, or can have, significant impacts on the restricted substance content in products during manufacturing or assembly;
- identification of product categories;

- definition of organizational systems, roles and responsibilities for implementation of RSC;
- appropriate specification from planning and design functions to give appropriate inputs to the procurement functions with regard to supplier RSC;
- confirmation of an effective process for the evaluation and selection of parts and materials;
- a review of operational process requirements (e.g. lead and lead-free process line segregation).

NOTE Annex A provides complementary guidance.

5.2 Sources of information/data

5.2.1 Data selection strategy

To ensure cost-effective flow of information, the producer should determine the likelihood of restricted substances being present for every material, part and sub-assembly included in the product.

Product evaluation for restricted substances may be based on a combination of several sources of information:

- supplier information;
- analytical testing;
- manufacturing and assembling operations, including incoming supply, process and delivery control.

It may not be possible or necessary to directly test every material, part and sub-assembly of a given product and test results only represent the status of the tested sample.

A combination of these information sources is generally needed. The likelihood of restricted substances being present in the product should be used to select the type and level of technical documentation that is required to confirm that restricted substance requirements are met.

The reasons for selecting the information sources should be documented and up to date.

5.2.2 Supplier information

For complex products, collection of supplier information avoids costly and repetitive testing of materials, parts and sub-assemblies. Collection of supplier information should follow industry standards, where available, to minimize supply chain impact and ensure consistent and cost-effective flow of information throughout the supply chain.

Types of documentation that may be obtained from suppliers include:

- supplier declaration of conformity or certificate of conformity from the supplier specifying the restricted substance content of the material, part, or sub-assembly;
- material declaration data sheet (provides information on specific substance content);

NOTE 1 Future IEC 62474 for "Material declaration" includes in its scope material declaration data sheets. Future IEC 62474 will replace and make obsolete IEC/PAS 61906.

NOTE 2 Joint Industry Guide (JIG), JGPSSI, IPC 1752, etc. are examples of material declaration data sheets.

- analytical test results (see Clause 6 for limitations and recommended uses);
- signed contract specifying restricted substance content of material, part, or sub-assembly;

- supplier audits and/or evaluation reports.

When using information provided by suppliers, the producer shall evaluate the information to ensure that it meets the requirements defined within the producer's procedures. The requirements should be based on standards, where available. The producer should also ensure that those suppliers have implemented acceptable RSC. To determine an acceptable procedure for a supplier's product, the producer should assess the likelihood of the procured parts or products containing restricted substances. The producer may judge this potential based on:

- material types used for the part and/or product and historical likelihood of restricted substances being present in these material types;
- information provided by supplier;
- historical experience with supplier organization.

For material declaration data sheets, the list of declarable substances represented, the declaration definitions and assumptions and the data format should be considered for alignment with industry standards. When an organization's policy requires the control of additional substances, these additional requirements should be communicated to the suppliers and should be considered in the evaluation of material declaration information.

When supplier information does not meet the producer RSC requirements, or if there is a likelihood that the procured product materials, parts and sub-assemblies contain restricted substances, the producer should consider obtaining additional supplier information, analytical testing or using alternate evaluation methods to meet the substance restriction requirements.

5.2.3 Analytical testing

Analytical testing techniques may be used to measure the concentrations of restricted substances in prepared samples. Specific testing techniques and sample preparation methods are generally required for different types of materials. Sampling and sample preparation are critical to the accuracy of analytical tests. Analytical testing of electrical and electronic parts and equipment should follow industry standards on sample collection, preparation and testing methods, where available.

For products that are composed of multiple materials, disassembly of the product and sampling of the materials may be necessary, depending on the substance restriction requirements. IEC/PAS 62596 provides guidelines on methods and limitations on product disassembly, disjointment and sampling in preparation for analytical testing.

IEC 62321 specifies methods and recommendations for sample preparation and analytical testing for certain restricted substances typically found in electrical and electronic products. This technical report defines methods for screening and verification testing. Screening tests can be a cost-effective tool to help identify areas of concern (parts and materials) that require further verification testing. However, screening tests are generally limited in accuracy and the ability to identify specific substances. Verification testing may be required when inconclusive results are obtained. IEC 62321 may be consulted for additional information.

Testing for substances restricted at the homogenous material level may be used in conjunction with supplier information. It is generally not desirable, cost-effective, nor practical to carry out analyses on all restricted substances in all product parts present in a typical electrical or electronic product. Therefore, the producer may develop a testing program based on factors such as:

- The part or material is judged to have a high probability of containing restricted substances based on history of usage of restricted substances in product materials, parts and sub-assemblies.

- Knowledge of manufacturing processes and possible sources of contamination and/or parts mixing (testing is used as part of the control of the producer's manufacturing and/or assembly operation).
- Supplier documentation is missing or of poor quality.
- Supplier has been judged by the producer to have potential non-conformities based on previous evaluations.
- Knowledge of analytical technique limitations (i.e. screening tool detection limits for certain substances may lead to inconclusive results which require further analysis).

Analytical testing may also be used as a tool to support the producer's restricted substance controls for manufacturing and/or assembly operations. Such testing may be part of the producer's overall strategy, but is not a specific requirement of this technical report. Analytical testing during a manufacturing or assembly operation may be an appropriate evaluation tool in the following situations:

- Incoming materials, parts and sub-assemblies inspections and screening where probability of restricted substances being present is high and/or random inspections.
- In-process quality control; strategy for manufacturing and/or assembly processes where parts mixing and/or cross contamination are possible (e.g. soldering operations etc).
- Final product screening prior to shipment to ensure no parts mixing.

Analytical testing as a method of evaluation may be appropriate for raw materials, simple parts or products that can be entirely disassembled into sufficient quantities of homogenous materials for testing. For complex electrical and electronic products, however, analytical methods can only be applied to a limited number of product parts sampled for analysis.

Analytical testing has the following limitations for substances restricted at the homogenous material level:

- Practicality in obtaining sample(s) that represent every type of discrete homogenous material of the product.
- Single products may not contain sufficient sample quantities for the prescribed analytical techniques.
- When destructive methods are required due to the shape of the sample/product or the kinds of substances to be analysed, the functionality of the product unit being evaluated is compromised.

Analytical results are specific to the sample, batch or product being tested and may not be representative of other units produced.

The contents of a test report will vary based on substances tested, the type of test being performed (e.g. screening vs. verification test), test method, test sample, customer requirements and any other factors that may be relevant to the test results. When evaluating test reports as part of RSC, the elements given in Annex B should be available and reviewed in the test report.

5.2.4 Manufacturing and assembling process information

In the manufacturing and assembling process there are many possibilities where restricted substances could be introduced into the product. The producer should identify where contamination of the product may occur in his handling, manufacturing and/or assembly operations. For example, contamination sources may be the result of

- a) material, part or sub-assembly from supplier not being compliant with the producer's specifications,
- b) manufacturing and assembly operations having different substance restriction requirements applied within the same plant .

The producer should determine the extent of RSC verification that is needed for their supply chain and internal production processes. The producer should ensure that, as a minimum:

- incoming materials, parts and sub-assemblies meet specified restricted substances requirements;
- measures are put in place so that all warehouse and production processes within its responsibility are controlled. The producer should prevent and/or correct contamination due to incorrect usage of manufacturing processes, tools and/or mixing of parts where controlled substances are used;
- employees receive relevant training or information.

If production functions are outsourced, the producer should require the outsourced manufacturing vendor to have the required controls and procedures described in these guidelines. In this case the producer should periodically check and document that outsourced manufacturers are following documented RSC procedures.

The producer shall ensure that final products meet the specified criteria for restricted substance content. The producer should identify products which do not meet the restricted substance requirements and control delivery of those products.

Types of documentation that may be obtained from suppliers to demonstrate restricted substance controls for manufacturing and assembling operations are

- producer self-declaration of RSC elements integrated with a quality, environmental or other management system certification,
- producer “RSC procedure” for organizations without a management system.

5.3 Product evaluation

The producer shall carry out an evaluation of a product based on information acquired according to 5.2. The points to be checked are as follows:

- sufficient valid information is available for all the materials, parts, and sub-assemblies composing the product; and
- all the materials, parts, and sub-assemblies meet restricted substance requirements

If a satisfactory result is not achieved the producer may decide that additional information/data is needed. It is necessary then for the producer to re-evaluate the obtained information/data.

With regard to substance use restrictions, the producer should re-evaluate the product whenever aspects that could impact the use of restricted substances occur, such as:

- if the restricted substance requirements change; or
- if supplied materials, parts and sub-assemblies change; or
- if manufacturing and assembly operations change.

The producer should perform this evaluation process before starting mass production of the product.

6 Documentation of evaluation results

When legal and customer requirements do not ask for a declaration, “presumption of conformity” applies, which means that requirements are deemed fulfilled without producer self-declaration.

On request, the producer may issue a producer self-declaration.

If further information is required, the producer should be able to provide technical documentation.

Upon customer request, the producer should be able to show that RSC elements required in this technical report have been implemented.

If a producer does not have an existing quality, environmental or other industry recognized management system in place – or he decides not to integrate the RSC – product level documentation may be used to demonstrate evaluation of a specific product. The producer should be able to provide documentation on the procedures which briefly describe how the organization meets the requirements of this technical report.

NOTE The latter approach may be more appropriate for small and medium size enterprises.

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Annex A

(informative)

RSC content vs. existing industry ISO management system references

Clause	IEC/TR 62476	ISO 9001 references (subclause)	ISO 14001 references (subclause)
4	Framework for evaluation of product The producer shall define and execute restricted substance controls (RSC) for the operations related to its product category under consideration and ensure the execution of adequate RSC by other producers in the supply chain. When evaluating a product, the producer shall have a level of technical documentation that demonstrates effective RSC	5.1 Management commitment	4.2 Environmental policy
5.1	Product planning and design consideration	5.2 Customer focus 5.4.1 Quality objectives 7.1 Planning of product realization 7.2.1 Determination of requirements related to the product 7.2.2 Review of requirements related to the product 7.3.1 – 7.3.6 Design and development: planning, inputs, outputs, review, verification and validation	4.3.1 Environmental aspects 4.3.2 Legal and other requirements 4.3.3 Objectives, targets and programmes 4.4.1 Resources, roles and responsibility and authority 4.4.6 Operational control
	Define legal, customer and other substance content requirements		
	Define organizational systems, roles and responsibilities for restricted substance management		

Clause	IEC/TR 62476	ISO 9001 references (subclause)	ISO 14001 references (subclause)
	Ensure an effective design process for the evaluation and selection of materials, parts and sub-assemblies, including the following elements: – a method or tool for designers to avoid inherently non-conforming parts or materials in their design; – the evaluation of materials, parts and sub-assemblies for meeting substance control requirements; – confirmation of RSC design process effectiveness and requests for improvement when necessary		
	Review of operational processes requirements (e.g. Lead and lead-free process lines segregation)		
5.2.2	Supplier information	7.4.1 Purchasing process 7.4.2 Purchasing information	
	Ensure an effective supplier RSC, which includes the following elements: Require appropriate RSC for all suppliers who provide materials, parts and sub-assemblies that constitute the producer's final products. Evaluate and select material part and sub-assembly suppliers based on their ability to supply products to the producer that conform to the producer's RSC standards. Confirm supplier RSC effectiveness and require improvements when necessary		
5.2.4	Manufacturing and assembling process	7.4.1 Processing process 7.4.2 Purchasing information 7.4.3 Verification of purchased product 7.5.1 Control of production and service provision 7.5.2 Validation of process for production and service provision 7.5.5 Preservation of product	4.4.6 Operational control
	Ensure incoming materials, parts and sub-assemblies meet specified restricted substances requirements		
	Ensure chemical changes are managed for manufacturing processes that change the nature of chemical substances or change the concentrations of chemical substances as a result of chemical reactions		

Clause	IEC/TR 62476	ISO 9001 references (subclause)	ISO 14001 references (subclause)
	Ensure measures are put in place to prevent the incorrect usage of manufacturing processes or mixing of parts where controlled substances are used		
		7.6 Control of monitoring and measuring devices Clause 8: Measurement, analysis and improvements 8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of product 8.4 Analysis of data	4.5.1 Monitoring and measurement 4.5.2 Evaluation of compliance
	The producers shall establish a system to review that final products meet the RSC requirements. The review system will identify products which do not meet the RSC requirements and control those products to prevent their unintended use or delivery		

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