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Indian Standard

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Test Method Development — Guidelines for Substance Selection

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NATIONAL FOREWORD

This Indian Standard which is identical to IEC TR 62936 : 2016 ‘Test method development — Guidelines for substance selection’ issued by the International Electrotechnical Commission (IEC) Was adopted by the Bureau of Indian Standards on the recommendation of the Standardization of Environmental Aspects for Electrical and Electronics Products Sectional Committee and approval of the Electrotechnical Division Council.

The text of IEC standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to thoseused in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words ‘International Standard’ appear referring to this standard, theyshould be read as ‘Indian Standard’; and

b) Comma (,) has been used as a decimal marker, while in Indian Standards the currentpractice is to use a point (.) as the decimal marker.

In this standard, reference appears to International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 62474 : 2012 Material declaration for products of and for the electrotechnical industry	IS 18051 : 2022/IEC 62474 : 2020 Material declaration for products of and for the electrotechnical industry	Identical

Only the English language text has been retained while adopting it in this Indian Standard, and as such, the page numbers given here are not the same as in the IEC publication.

For the purpose of deciding whether a particular requirement of this standard is complied withthe final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding of numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of thespecified value in this standard.

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INTRODUCTION

The large number of chemical substances currently regulated or under consideration for regulation necessitates the need for the development of reliable and acceptable test methods to be used as one approach for conformity assessment. For conformance demonstration, it is vital that interested parties agree that a particular test method is technically correct (i.e. provide reliable analytical results), is appropriate for the samples to be analysed, tested and vetted by technical experts, and is unbiased in its application. These criteria are generally fulfilled by test methods that are developed and published by a standards development organization (SDO) (e.g. IEC, ISO). Because of limited resources and the length of time needed to develop and validate these procedures, only a limited number of substances can be addressed at any given time for test method development.

This document provides a process for logically filtering, prioritizing and selecting candidate substances for development of test method standards. The objective of the filtering process is to partition the list of candidate substances into groups based on relative importance. Given that this document is intended for electrotechnical products, the candidate substances are largely drawn, but not exclusively, from the substance lists recorded in the IEC 62474 database [1][1] on material declaration. The substances listed in the database are grouped into 3 categories with brief descriptions given below:

- IEC Criteria 1 – “currently regulated” or “explicitly included within an existing national law or regulation in an IEC member country”. The law or regulation is applicable to electrotechnical products and goes into force at a specific date.
- IEC Criteria 2 – “for assessment” or substance or substance group that meets criteria 1 with the exception that the law or regulation does not cite a specific effective date for the requirements.
- IEC Criteria 3 – “for information only” or does not meet requirement for either criteria 1 or 2. However, “there is a recognized industry-wide common market requirement for reporting this substance or substance group in electrotechnical products”.

NOTE Criterion/criteria is used in this document to denote a rule/principle for evaluating a substance against a set of requirements. The use of the term IEC criteria is specific to the regulatory status of a particular substance as defined in the IEC 62474 standard.

In addition to those substances that are under regulatory scrutiny, market requirements may also be of major consideration for the development of IEC test method standards. There are several very important influences that may dictate the ability of a product to enter or be introduced into the marketplace. Examples of market driven requirements may include EPEAT® (Electronic Product Environment Assessment Tool), Low Halogen initiative set by the electronics industry, Energy Star® [2] for energy efficient products and others. Although there are no legal obligations that electrotechnical equipment meet the requirements set forth in these initiatives, failure to do so may put the supplier at a severe competitive disadvantage. In many cases, the supplier’s product may be disqualified for purchasing consideration for failure to meet these requirements.

The filtering process is intended to screen out the majority of substances for consideration leaving only the “critical few” substances for further consideration. Due to the rapidly changing regulatory environment, the criteria used for filtering may or may not be the most appropriate for the substances under consideration. Thus, some judgement needs to be exercised in interpreting the resulting scores. The final selection process is intended to allow the consideration of additional requirements or criteria that are not captured in the initial filtering process. Subjective criteria (relative importance is not measureable) may also be introduced. No attempt has been made to try to define the criteria in the final selection process given the changing requirements in both the regulatory and market environments.

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1 Numbers in square brackets refer to the bibliography.

2 EPEAT and Energy Star are registered trademarks. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these registered trademarks.

Indian Standard

TEST METHOD DEVELOPMENT — GUIDELINES FOR SUBSTANCE SELECTION

1 Scope

This document provides guidelines for the selection of substances for the development of test method standards. The substances and substance groups listed in the IEC 62474 database are the primary source of candidate substances. Other substances that are under regulatory roadmap and market requirements can also be considered for this filtering and selection process.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.2 Abbreviated terms

CMR	carcinogenic, mutagenic or toxic to reproduction
CoRAP	community rolling action plan
EEE	electrical and electronic equipment
REACH	registration, evaluation, authorization and restriction of chemicals
RoHS	restriction of hazardous substances
SDO	standards development organization
SIN	substitute it now
SVHC	substances of very high concern

4 Process flow

Substances that are contained in the IEC 62474 database have undergone technical scrutiny to determine applicability to electrotechnical products. This vetting process provides an effective first screen to narrow down the potential number of substances that may be considered for test method development within IEC. Specifically, these substances have been evaluated by technical experts to be used in electrical and electronic equipment (EEE) products. This type of assessment will need to be performed for substances that are not

contained in the IEC 62474 database. A conceptual flow for the general substance selection decision making process is given in Figure 1.

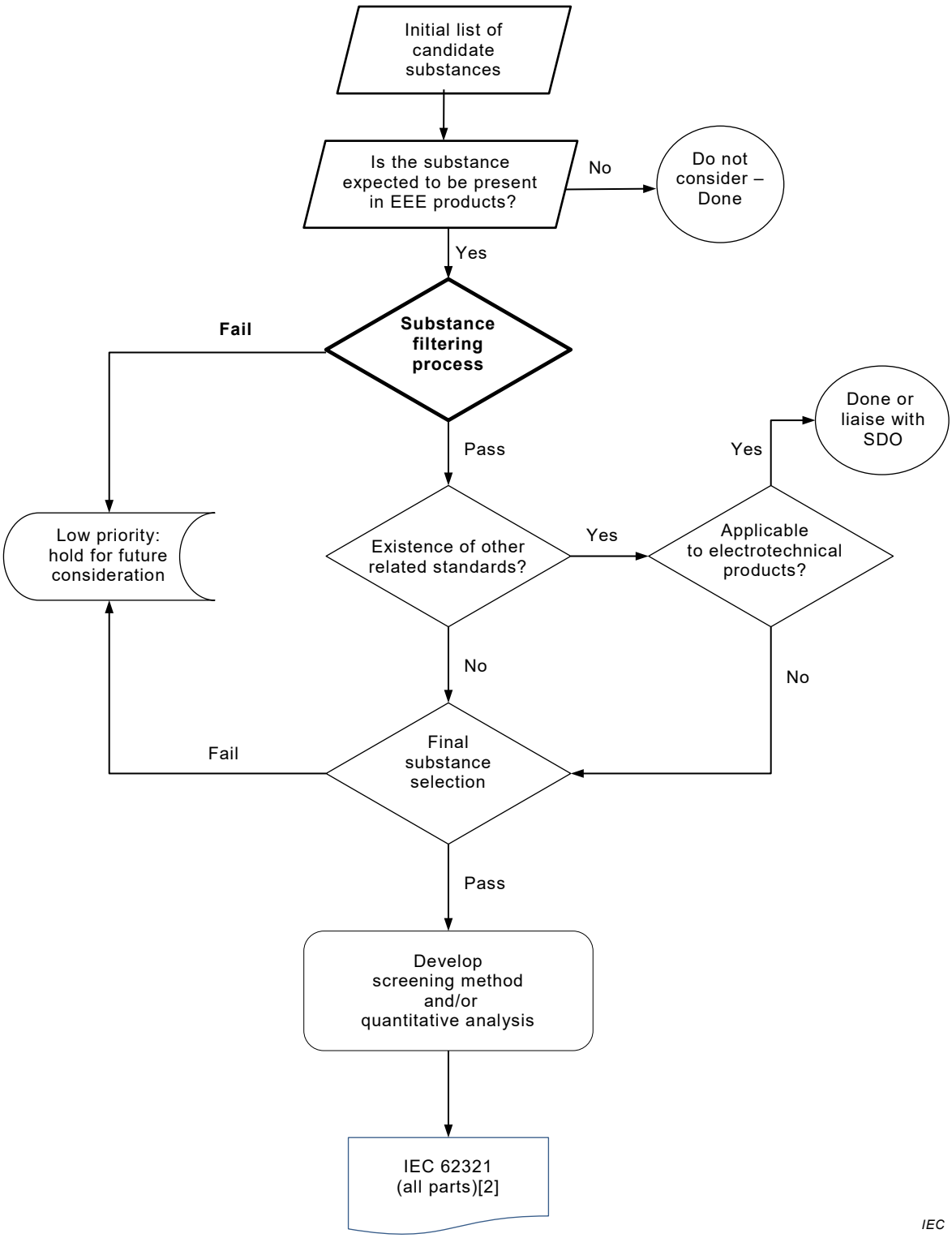

Figure 1 – Substance selection process

5 Process flow steps

5.1 Chemical substance list

Substances under consideration for test method development are found in the IEC 62474 materials declaration database and other readily available sources. The IEC 62474 database is generally the initial source of information since it provides a vetted and frequently updated list of substances that is under scrutiny by either having regulatory obligations associated with them or potentially will be in the future. Given the large number of substances either being regulated or under consideration for regulation, this database provides an effective screening of substances present in electrotechnical products. The IEC 62474 validation team is responsible for maintenance of the materials declaration database.

5.2 Substance filtering process

Given the large number of substances that are potential candidates for test method development, a systematic approach is needed for reducing the number of candidates for consideration before final selection. This can be accomplished by employing a filtering process. The basis of the filtering process is to apply a set of criteria that defines the timeliness and impact for test method development for a particular substance. Important categories for the filtering criteria include:

- presence of substance in the final product;
- regulatory or market requirements;
- regional impact;
- regulatory impact;
- intentional addition of substance;
- strategic or future impact;
- test method development.

Table 1 details the criteria and associated weighting factors to be used in the filtering process. Note that the criteria pertaining to “regulatory or market requirements” and “regulatory impact” are assigned scores based on the information used by the IEC 62474 validation team for assessing which substances are added to the database. For substances not listed in the database a similar assessment will need to be performed. The list of criteria and its relative weighting will be revised annually since the regulatory environment is dynamic. The weighting factors used are adopted from the Quality Function Deployment/Six Sigma methodology [3], [4]. Although the output from this process is a scoring for the substances under consideration, its intention is only to identify those substances where test method development would be most impactful or provide the most value to the electrotechnical industry. Technical Committee (TC) 111 will be tasked to determine, based on the scored list, which substances will be included in the final selection process.

Table 1 – Substance filtering criteria

Criterion	Weighting factor	Comments
Substance presence		
Is substance expected to be present in the final EEE product?	Yes/No	If a substance fails this criterion it will be eliminated as a candidate for the process.
Regulatory or market requirements		
Substance is currently under regulation – Criteria 1 or market requirements or other forces make it mandatory to self-regulate substance. Impact to business is high.	9	For substances that are regulated but not necessarily restricted.
Substance will be under regulation – Criteria 2 or market requirements or other forces make it highly advantageous to self-regulate substance. Impact to business is moderate.	3	No timeframe defined but substance on watch list; substance will be added to a designated list.
Substance has no timeline for regulation to be in force – Criteria 3 or market or other forces make it desirable but not necessary to regulate. Impact to business is low.	1	Also includes substances that have been phased out but may still be in products in use. Substance may not be regulated but could represent a disposal hazard.
Regional impact		
Global	9	Multi-country or region: 2 or more.
Regional	3	Country or region specific.
Local	1	Within a country.
No impact	0	Substance impact is undefined or very low.
Regulatory impact		
Criterion 1: Substance is restricted	9	Threshold limit is established
Criterion 2: Substance is not restricted but requires reporting or other regulatory obligation.	3	Threshold limit is established
Criterion 3: Substance does not have any regulatory obligations.	1	No restrictions
Intentional addition of substance		
Is the intentionally added substance expected to be present in the final product above threshold?	3 or 1	Substance of interest would be expected to be present in final product at levels above threshold. Yes = 3 No = 1
Strategic considerations		
Substance is currently IEC 62474 criteria 2 or 3 but has the following attributes: – Industry accepted test method standard not available and not currently under development. – Widely used in EEE. – Substance is anticipated to be important for new or emerging markets e.g. wearable electronics. – Need to recover high value substances e.g. precious metals. – High degree of confidence that substance will be regulated within 3 to 5 years.	9,3,1	Early identification of substances that is important to the electrotechnical industry but not currently regulated. These substances may be considered high risk for future regulatory or market driven requirements. NOTE If the substance is not criteria 2 or 3, it will be assigned a 1. 9 = meets ≥ 4 criteria 3 = meets 2 or 3 of criteria 1 = meets 0 or 1 criterion
Test method development		
TM1: Is there a viable approach for testing the substance of interest?	3 or 1	Criterion that helps to define probability of success for development Yes = 3 No = 1

Criterion	Weighting factor	Comments
TM2: Can the test method be applied across multiple substances or a group of chemically similar substances?	3 or 1	For example, classes of substances such as phthalates, PAHs. Yes = 3 No = 1
TM3: Is the proposed test method for a particular substance or substance group implementable for conformity assessment?	3 or 1	Cost effective, safety, etc. need to be considered. Yes = 3 No = 1

5.3 Substance filtering criteria

5.3.1 Substance presence in final EEE product

This criterion is the first filter since the intent is to only choose substances that are expected to be present in the final end product. Substances that are used as process chemicals in the manufacture of the product but are either removed or chemically transformed in the final product are outside the scope of this process. This step is also one of the criteria used by the IEC 62474 validation team to determine its inclusion into the declaration substance list database.

5.3.2 Regulatory or market requirements

The regulatory status and timetable for enforcement of a substance may define the need for test methods to support conformity assessment. Reporting and/or restriction of a substance may require validation through chemical analysis. The greater the regulatory requirement is, the greater the need is for available assessment capabilities. For this document, the categorization of the substance criteria is taken from the definitions in IEC 62474 as defined by IEC Criteria 1, 2 and 3 (see Introduction). Additionally, the criteria are expanded to include voluntary requirements which may include some regulatory and non-regulatory requirements. Market requirements would fall under this category since they may also be an important consideration for test method development. Although they are not necessarily legal requirements in nature, they may greatly impact the ability of a product to enter a market. Examples of market driven requirements include the Low Halogen initiative, EPEAT® and others where substance type and concentration within a product may have defined allowable threshold values. Compliance to these market requirements are often used as a means for ensuring the procurement of EEE of demonstrated environmental “green-ness”.

5.3.3 Regional impact

This criterion defines the geographical impact of a regulation. The scope of a particular regulation has been defined in this criterion to be local, regional or global. The greater the geographical reach of the regulation the higher the assigned scoring for this criterion. For example, RoHS would be considered a global regulation although it originates from the EU. Many other countries particularly those in Asia are adopting their own version of RoHS. Although the details among the different country regulations may be different, the basic requirements are consistent. Alternatively, California Proposition 65 [5] is specific to products being sold in that locality. Its requirements are particularly unique with respect to the list of substances within its scope, the requirements concerning reporting, threshold levels and many others. For this example, it would be scored as a local impact since it is unlikely to be adopted outside of the United States in the foreseeable future.

5.3.4 Regulatory impact

Criterion 1 in this scoring category differentiates between substances whose presence in electrotechnical products is restricted and those that only require reporting or labelling. Restriction of substance in a product is more impactful than having to only report its presence through declarations or labelling. This criterion categorizes the substances according to the

regulatory obligation that is placed on the supplier. Most severe in terms of regulatory impact would be prohibition or restriction of a substance in a product. The requirement to report the presence of a substance above a defined threshold limit without restricting the use of that substance in a product is deemed less severe (Criterion 2). No regulatory requirement for a substance is considered the least impactful and would score the lowest as defined by Criterion 3. An example of a Criterion 1 regulation would be RoHS which restricts certain substances to a defined threshold limit. REACH SVHC candidate substances would fall under Criterion 2 since these substances are not banned or restricted but do require reporting when present in the product above the defined threshold limit.

5.3.5 Intentional addition of substance

This criterion is meant to capture those situations where a regulated substance is intentionally added to produce the final product. This substance is not a process chemical and its presence in the final product is expected. This criterion defines two situations where a substance is intentionally added:

- concentration is expected to be above threshold;
- concentration is expected to be below threshold.

The unintentional presence of a substance in the final product may result from contamination, by product formation during processing and manufacturing, incomplete chemical reactions or any other situation where the presence of the substance would not normally be expected above threshold.

NOTE For substances that are not regulated, the threshold of the potentially applicable regulations and requirements could be used for scoring.

5.3.6 Strategic considerations

This criterion is in place in order to identify substances that are expected to have a regulatory impact at some time in the future. Early identification of these substances will allow time for development of test method standards hopefully in advance of the regulatory requirements being placed in force. In essence, this list of substances could constitute a roadmap for strategic planning of activities for TC 111.

It shall be noted that the attempt to predict which substances will be important from a regulations perspective is inherently risky. A substance may be considered as a strong candidate for future regulation today but over time may lose that importance due to a variety of factors such as voluntary phasing out of the use of that substance, new data or evidence that alters the hazard profile of that substance, alternatives that encourage the elimination of a substance used in a product, etc. There is no guarantee that a substance that is rated high from a strategic impact point of view will be placed under regulatory control.

IEC Criteria 3 substances are not currently regulated or under any defined timetable for regulation. Because the process for placing a substance under regulation is generally in the order of years, there may be sufficient time to develop an analytical test method prior to the regulation going into force. Substances that are classified as IEC Criteria 2 would also qualify if the lead time for the enforcement of the regulation of those substances is sufficiently long, i.e. several years or more. Substances that qualify under this criterion are expected to exhibit the following attributes:

- industry accepted test method standard not available and not currently under development;
- widely used in electrotechnical equipment;
- will be important for new or emerging market (e.g. wearables);
- high value making recovery at end of life economically feasible (e.g. precious metals);
- very high likelihood that the substance will eventually move to IEC Criteria 1.

A more detailed description of the attributes is given below.

- Test method standard not available – since the substances under this category are not currently regulated, it is very likely that the industry accepted test method standard is not available or under development. Therefore, there is a gap and meanwhile this is an opportunity for an IEC test method standard to be developed.
- Widely used in EEE – the definition of “widely used” is somewhat subjective. Depending on the substance “widely used” could denote the total mass (weight) used in EEE or the total number of units that incorporate the substance into the final product. This criterion shall also incorporate the anticipated future use of this substance which may be considerably greater (or less) than its current use. Generally, good information/data that would allow this criterion to be evaluated may be hard to obtain.
- New and important uses – innovation leads to the development of new technologies and products. Consequently, the use of substances that have not been traditionally incorporated into EEE may now become an important ingredient for the new technology or product type.
- High value – substances under this category are generally considered to be of high monetary value so that the cost of reclaiming and/or recycling of the substance(s) would be worthwhile. Obvious examples of substances that are of high monetary value include precious metals. Substances that are expensive to synthesize or manufacture may also fall into the category of high value.
- Promotion to regulated status – this condition is denoted as IEC Criteria 1. There shall be reasonable evidence or high confidence that the substance will be regulated some time in the future. A targeted timeframe would be in the order of three to five years. Any timeframe much beyond three to five years would run the risk of having a test method developed well in advance of the substance being regulated.

  Many substances which would qualify for strategic considerations are found in various lists of verified or suspected hazardous substances. These lists originate from various sources including industry groups, non-government organizations, government groups and others. Among the more prominent published lists are the REACH CMR list, CoRAP lists, RoHS II proposed substances, SIN (substitute it now!) list to name a few. To some extent, these lists help to provide some visibility into the future concerning which substances may be on the horizon for regulation.

5.3.7 Test method development

This criterion is predicated on several considerations:

- Test method viability – given the length of time required to develop a test method and to convert it into an industry standard, it is important that the probability of success be reasonably high. In most cases, the feasibility and utility of the proposed test method has been previously demonstrated as evidenced by published scientific literature, equipment vendor’s application notes, and/or other verifiable sources.
- Applicability of the proposed test method – is it applicable to a single substance only or can it be used across a class of substances? The value of the test method increases as the potential number of substances within its scope increases. An example of a very specific test would be the colorimetric method using diphenylcarbazide for the analysis of hexavalent chromium. This test method will only detect chromium in its +6 oxidation state. Therefore, the scope of applicability of this technique is limited to one element that is in a specific oxidation state. This limited scope would not necessarily preclude its consideration for test method development given the prevalent use of hexavalent chromium compounds and the health hazards that it presents. Methods that are applicable to a larger number of substances or substance group would provide a greater level of overall capability relative to a single specific method.
- Implementation – The test method should be implementable based on cost, safety and technical considerations for most working industrial or government laboratories. Equipment necessary to perform the analysis should be commercially available and commonly used. Safety considerations for the analyst are of the utmost importance. Exposure of laboratory personnel to unsafe practices and environments should not be acceptable.

NOTE A number of other criteria were considered but not incorporated into the process due to the inability to objectively determine its importance. These considerations could include how easily the substance can be substituted for its intended use, its recyclability for reuse, whether the substance is critical to function for a particular application, etc. They could be included in a subsequent revision of the document when it becomes possible to consistently and objectively score the criteria.

Relative ranking is based on the cumulative weighted score for each substance versus the filtering criteria. However, the filtering process is not intended to provide a prioritized list with the substance attaining the highest score being the highest priority for test method development. Rather it is intended to separate the critical few substances versus the lesser important substances based on the filtering criteria. It will be at the discretion of TC 111 to determine the number of substances that pass into the final selection process. It is anticipated that the filtering process will result in an obvious grouping of substances. The cut-off score for grouping is arbitrarily set as 30. The substances scored higher than 30 are considered as Pass (Group 1) in the substance filtering process.

A strict priority ranking process would require that all key criteria be included and scored appropriately. Given the dynamic regulatory and market environment, the relative importance of the selected criteria can change with time. The final selection process will take into consideration factors that are not captured in the filtering process as a result of new requirements or other contingencies. Substances that are deemed low priority for immediate action could be reconsidered at a later date.

5.4 Existence of other related standards

Many substances in the IEC 62474 database have test methods already developed by a standards developing organization (SDO) or by other entities such as government laboratories. The applicability of these test methods for use in conformance assessments of electrotechnical products may be sufficient to meet the need. In this case, development of new test methods may not be warranted. For test methods under development by an SDO that would meet the basic requirements for electrotechnical products, it may be appropriate to liaise with that organization. This cooperative/collaborative partnership may provide benefits to both TC 111 and the other SDO. For substances where no viable test method standard is available, then this substance would deserve further consideration for test method development.

5.5 Final substance selection

At this point in the process, the substances of greatest relevance for test method development should be clearly identified. The expectations are that the number of substances for the final selection process would be such that a decision can be reached with a reasonable amount of time and effort. The final selection process is used to introduce any additional considerations or factors that were not included in the filtering process. These considerations may represent special circumstances or unique requirements that are timely to the decision making process. As an example, the availability of the appropriate technical resources to engage in the test method development project may determine its feasibility. Other factors may also be introduced that can either prioritize or de-prioritize the selection of a certain substance(s). It will be the responsibility of TC 111 to consider and propose the substance or substances that will be recommended for test method development.

Annex A
(informative)

Pilot study of RoHS II priority substances

Table A.1 is the pilot study result of RoHS II priority substances by following the substance selection process outlined in Figure 1 and applying the filtering criteria in Table 1. The substances are not considered for the filtering process if they are not expected to be present in EEE products. The other substances are categorized into two groups based on the scores. The Group 1 substances pass the substance filtering process and will be subject to a final selection process to determine the necessities and possibilities of test method development.

Table A.1 – Pilot study result of RoHS II priority substances

Candidate substance	Expected in EEE product?	Regulations / Market	Regional impact	Regulations impact	Substance addition	Strategic	TM (1)	TM (2)	TM (3)	Total	Grouping
Diisobutylphthalate (DIBP)	Yes	9	9	9	3	1	3	3	3	40	1
Tris(2-chloroethyl) phosphate (TCEP)	Yes	9	9	3	3	1	3	3	3	34	1
Dibromo-neopentyl-glycol	No										
2,3-dibromo-1-propanol (Dibromo-propanol)	No										
Antimony trioxide	Yes	9	1	3	3	1	1	1	3	22	2
Diethyl phthalate (DEP)	Yes	1	0	1	3	3	3	3	3	17	2
Tetrabromobisphenol A	Yes	9	0	1	3	9	3	3	3	31	1
MCCP (medium chained chlorinated paraffins), C14 – C17: alkanes, C14-17, chloro;	Yes	9	0	1	3	3	3	3	3	25	2
Polyvinylchloride (PVC)	Yes	9	0	1	3	3	3	3	3	25	2
Nickel sulphate	No										
Nickel bis(sulfamidate); Nickel sulfamate	No										
Beryllium metal	Yes	9	1	3	3	1	3	3	3	26	2
Beryllium oxide (BeO)	Yes	9	1	3	3	1	1	1	3	22	2

Candidate substance	Expected in EEE product?	Regulations / Market	Regional impact	Regulations impact	Substance addition	Strategic	TM (1)	TM (2)	TM (3)	Total	Grouping
Indium phosphide	Yes	1	0	1	3	3	1	1	3	13	2
Di-arsenic pentoxide; (i.e. Arsenic pentoxide; Arsenic oxide)	No										
Di-arsenic trioxide	No										
Cobalt dichloride	No										
Cobalt sulphate	No										
Cobalt metal	Yes	1	0	1	3	1	3	3	3	15	2
Nonylphenol	No										

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[1] IEC 62474, *Material Declaration for Products of and for the Electrotechnical Industry* (database available at http://std.iec.ch/iec62474)

[2] IEC 62321 (all parts), *Determination of certain substances in electrotechnical products*

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[5] California Proposition 65, Safe Drinking Water and Toxic Enforcement Act of 1986, OEHHA

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