Designation: F2577 – 22

Standard Guide for Compositional Evaluation of Declarable Substances and Substances of Concern for Materials in Products[1]

This standard is issued under the fixed designation F2577; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide uses case studies to illustrate the decision process to assess materials and products for declarable substances when evaluating conformance to relevant requirements. This may be accomplished by applying existing knowledge to determine the need for further action (for example, testing).

1.2 This guide assists in utilization and interpretation of various forms of information gathered to enable compliance or conformance or both to regulations, standards, supply agreements, or customer enquiries related to identified declarable substances, including the evidence required to issue declarations for the absence or presence of a declarable substance. Several examples are referenced. The target declarable substances will be specific to the product and product classification, the regulatory jurisdiction, customer/supplier requirements, and other relevant considerations. Consideration of which regulations and standards apply to a given product is beyond the scope of this guide.

1.3 The framework covered in this guide attempts to harmonize language used in the absence of objective data or specific regulatory requirements or both. This guide draws on a variety of existing documentation, which will be cited and referenced, as well as basic scientific principles for communication of chemical hazard and risk, and may be used as an approach for assessing composition of products and their components as part of product risk assessment.

1.4 This guide is applicable to a variety of materials, including polymeric and elastomeric materials, which are used in regulated industries and products.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D883 Terminology Relating to Plastics

F2576 Terminology Relating to Declarable Substances in Materials

F2931 Guide for Analytical Testing of Substances of Very High Concern in Materials and Products

2.2 *IEC Standards:*[3]

IEC 62321-8:2017 Determination of certain substances in electrotechnical products Part 8: Determination of specific phthalates in polymer materials by mass spectrometry

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

2.3 *ISO Standards:*[4]

ISO 9001:2015 Quality management systems – Requirements

ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

ISO 14021:2016 Environmental Labels and Declarations: Self-Declared Environmental Claims

ISO 14971:2019 Medical devices – Application of risk management to medical devices

3. Terminology

3.1 *Definitions:* Terms and definitions related to declarable substances in materials may be found in Terminology F2576.

[1] This guide is under the jurisdiction of ASTM Committee F40 on Declarable Substances in Materials and is the direct responsibility of Subcommittee F40.02 on Management Practices and Guides.

Current edition approved Oct. 1, 2022. Published November 2022. Originally approved in 2006. Last previous edition approved in 2014 as F2577–14. DOI: 10.1520/F2577-22.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from the International Electrotechnical Commission, 3, rue de Varembé, 1st floor, P.O. Box 131, CH - 1211 Geneva 20, Switzerland, www.iec.ch.

[4] Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

3.1.1 Terms and definitions in the guide not found in Terminology F2576 may be found in a common dictionary or other reference documents such as Terminology D883 or the *ASTM Dictionary of Engineering Science & Technology* (Ref (**1**)).[5]

4. Significance and Use

4.1 Regulations, standards, and market-defined requirements for chemical constituent ("substances of interest") compliance and conformance have become increasing numerous and complex. Specific laws and standards may pertain to certain product and industry segments, for example, electrical/electronic instruments and components, pharmaceuticals, medical devices, consumer products, agrichemicals, and so forth. Others may be broader and relate specifically to assessment and management of specific chemical compounds or classes across multiple product sectors and sources, for example Ref (**2**). In addition, such requirements may be issued by national authorities, international standards setting groups, or, in the case of market-defined requirements, even by customer advocacy organizations or customers through supply contracts. The resulting global landscape of requirements and market access expectations is complex, and compliance/conformance presents numerous challenges for manufacturers.

NOTE 1—For example, IEC 62474:2012 provides some standardized definitions for reporting thresholds and declaration statements for electrotechnical industry. In another example, ISO 14021:2016 addresses self-declared environmental claims.

4.2 Declarable substances may be found on various lists and forms, including those listed in Refs (**2-10**) and on supply agreements and questionnaires. This guide is not intended to be exhaustive nor cover all declarable substances. Nor does this guide address specific declaration and labeling requirements within these regulation and standards nor address product safety and compliance requirements as dictated by law for specific products, industries, or market regions.

4.3 In addition to new laws and standards, more chemical substances are continually added to a variety of screening lists for review of potential hazards, identification and quantification of possible health or environmental hazards, or both, and consideration of control measures. To comply with these requirements, significant efforts are being directed to detailed data gathering throughout manufacturer supply chains, documentation of presence or absence of such declarable substances, and continual "update" maintenance of the resultant information. Standardized processes have been proposed to assess the potential for a material to contain a possible substance of interest/concern.

4.4 Because of requirements being placed on concentrations of declarable substances within (or on) materials, assessing conformance of products has become a complex, time-consuming, and expensive task. This guide is intended to assist the user in developing a protocol for product assessment. This guide is also directed toward interpretation and communication of the resultant information, specifically where clear objective/numeric data are not available or obtainable, and in the absence of directly applicable regulatory direction. This guide is intended to harmonize language used to interpret and communicate results of these formulation-based or direct-analysis based assessments. Examples include "not expected to contain," "not intentionally added," "not used in formulation," "below *de minimis* levels," "below analytical detection limits," "not toxicologically significant," "not material to safety," "free of," and so forth.

4.5 *A priori* knowledge is based on logical deduction and scientific principles, so actual testing of a material may not be required to assess conformance to requirements. For example, it is possible to deduce that organic substances will not survive the temperatures required to produce wrought steel, so there is no need to test for organic substances in wrought steel nor is it possible to develop test methods and reference materials for determination of organic substances within wrought steel.

4.6 *A posteriori* knowledge is based on observation, experience and known facts. If *a priori* knowledge cannot rule out the possibility that a substance is present within (or on) a material, a test method may be required to verify or generate information on the concentration of that substance within (or on) the material.

4.7 Statements provided by a manufacturer about declarable substances in a product may contain either or both *a priori* and *a posteriori* information. The recipient of such statements may be downstream manufacturers who incorporate multiple materials and components into other products with their own subsequent documentation on declarable substances. Each producer is responsible for its own products' substance declarations, including any potential inaccuracies that may be provided by suppliers. Thus, each manufacturer should take into account its suppliers' risk profiles when choosing to rely on supplier declarations.

4.8 Test methods can be used to verify and provide information related to substances within materials. At the same time, misinformation can be generated or inappropriate conclusions drawn when test methods are misapplied. This guide is intended to provide recommendations on the application of test methods.

4.9 Test methods may be applied by producers or by interim or end users of materials. However, it is not necessary or cost effective to test materials at each stage of production. The decision to apply test methods and the frequency of testing should be based on risk perceived by the user or can be a matter of agreement.

4.10 Assessment of different types and classes of materials each have their individual complexities and nuances given the advancements in both materials and analytical evaluation methods.

4.11 For some regulations and directives, a clear *de minimis* threshold has been defined for a substance or group of substances. In the absence of a prescribed *de minimis*, 0.1 % (w/w) is a suitable threshold.

4.11.1 The *de minimis* level may be described as an individual limit, or as an aggregated limit, whose details will be

[5] The boldface numbers in parentheses refer to a list of references at the end of this standard.

dependent on a specific regulation. In no instance shall an aggregated *de minimis* exceed the sum of the prescribed *de minimis* for the collective group of substances.

4.12 This guide includes a general process and case studies in order to provide guidance and to distinguish when *a priori* and *a posteriori* knowledge should be applied. Flow charts as a guide for assessment of materials and products are provided in Appendix X1.

5. General Process of Assessment of Materials and Products for Conformance with Requirements

5.1 The process of assessing materials and products for conformance with requirements may be broken down into the following steps:

5.1.1 Determine if the material or product is covered under the scope of the requirements, taking into account any exemptions from the scope.

5.1.2 Establish the basis of conformance to which limits for substances given in the requirements apply.

5.1.2.1 List each material to be assessed and assess each on an individual basis.

5.1.3 If appropriate, apply *a priori* knowledge of the material and its manufacture to assess the probability of whether each declarable substance may be present.

5.1.4 As necessary, obtain *a posteriori* knowledge of substance concentrations based upon observations or empirical data from the material.

5.1.5 Assess the material or product for conformance to requirements based upon *a priori* and *a posteriori* information.

5.1.5.1 If the basis of conformance to requirements is each material within a product, assess each material separately for declarable substances content.

5.1.5.2 If the basis of conformance to requirements is the entire product, assess the cumulative contribution of declarable substances in materials for the entire product.

5.1.6 Document the assessment process for each material or product.

5.2 Determine if the material or product is covered under the scope of the requirements, taking into account any exemptions from the scope. Requirements may be regulations or stipulations by clients, that is, they may be statutory or by agreement. The first step in any assessment is to determine what is covered by requirements or the scope of the requirements. In some cases, exemptions to the scope are allowed, so it is important to establish whether a particular material or product falls under the scope and whether the product or material is exempt from that scope.

5.3 Establish the basis of conformance to which limits for substances given in the requirements apply. Requirements in the form of substance restrictions or declaration limits typically list concentrations of substances above which the product or material is considered non-conforming or the substances shall be declared. It is important to determine the basis to which the limits apply to assess conformance properly. For example, the limits may apply to an entire product or they may apply to each material within the product.

NOTE 2—Limits of "zero" for substances or statements such as "products shall not contain" certain substances are indeterminate. Products or materials cannot be assessed to such limits without accounting for and identifying every atom constituting the product or material being assessed. See also 4.11.

5.4 If appropriate, apply *a priori* knowledge of the material and its manufacture to assess the probability whether each declarable substance may be present. Lists of declarable substances in requirements may have been set with little or no regard to material types to be assessed. Through application of *a priori* knowledge of specific materials it may be possible to eliminate the need to gather empirical data for certain substances listed in the requirements.

NOTE 3—*A priori* knowledge requires justification based upon scientific principles and logical deduction. For example, the statement that it is not necessary to determine the hexavalent chromium concentration within wrought metals is based upon knowledge of metallurgy and atomic structure.

5.5 As necessary, obtain *a posteriori* knowledge of substance concentrations based upon observations or empirical data from the material. Data on substance concentrations within or on materials may be obtained from suppliers in the form of material declarations or specifications; certificates of analysis; or a laboratory report of a lot, batch, or heat of material. While it is not necessary to confirm every certificate obtained from suppliers via repetition of testing, it is good practice to confirm material data periodically.

5.6 Assess the material or product for conformance to requirements based upon *a priori* and *a posteriori* information. The concentrations of any declarable substances in materials or products are compared to the limits set by the requirements to determine conformance or non-conformance. While *a posteriori* information in the form of empirical data may be directly compared to limit values, *a priori* information may indicate that it is not appropriate to assess conformity of materials for certain substances.

NOTE 4—*A priori* knowledge that a substance cannot be present in a material precludes the possibility of generating empirical data for that substance within that material. It is appropriate to state in such cases that conformity assessment is not applicable.

5.7 Document the assessment process for each material or product. Documentation in the form of data and illustration of the assessment process is necessary to back up statements of compliance for materials and products.

6. Keywords

6.1 compliance; conformity assessment; declarable substances; *de minimis*; material declaration; product testing

APPENDIXES

(Nonmandatory Information)

X1. FLOW CHARTS

X1.1 See Fig. X1.1 and Fig. X1.2.

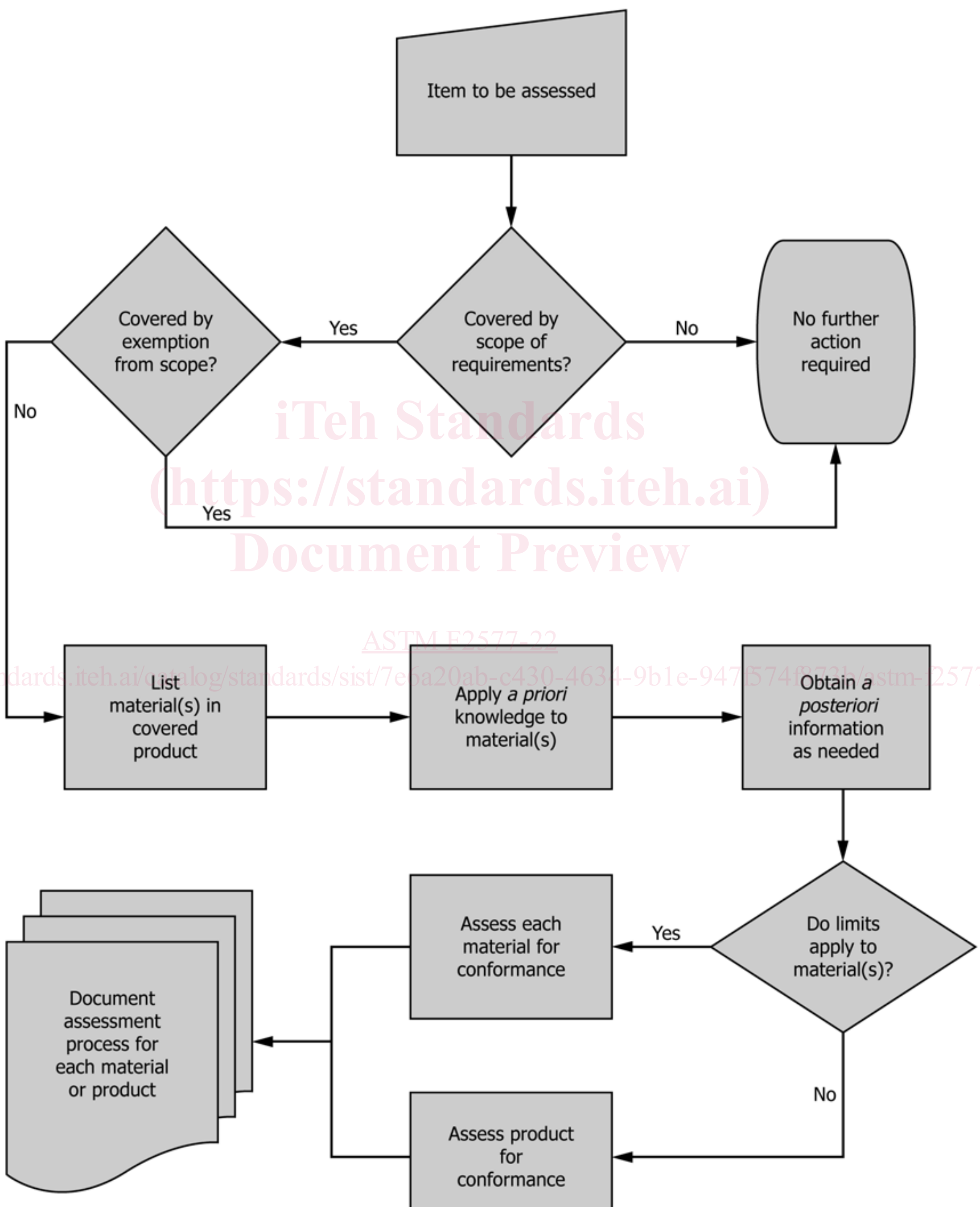

FIG. X1.1 Flow Chart Illustrating the General Process of Assessment of Materials and Products for Conformance with Requirements

An example of a flow chart designed to clarify the compliance process and help producers determine when analysis of components might be advisable.

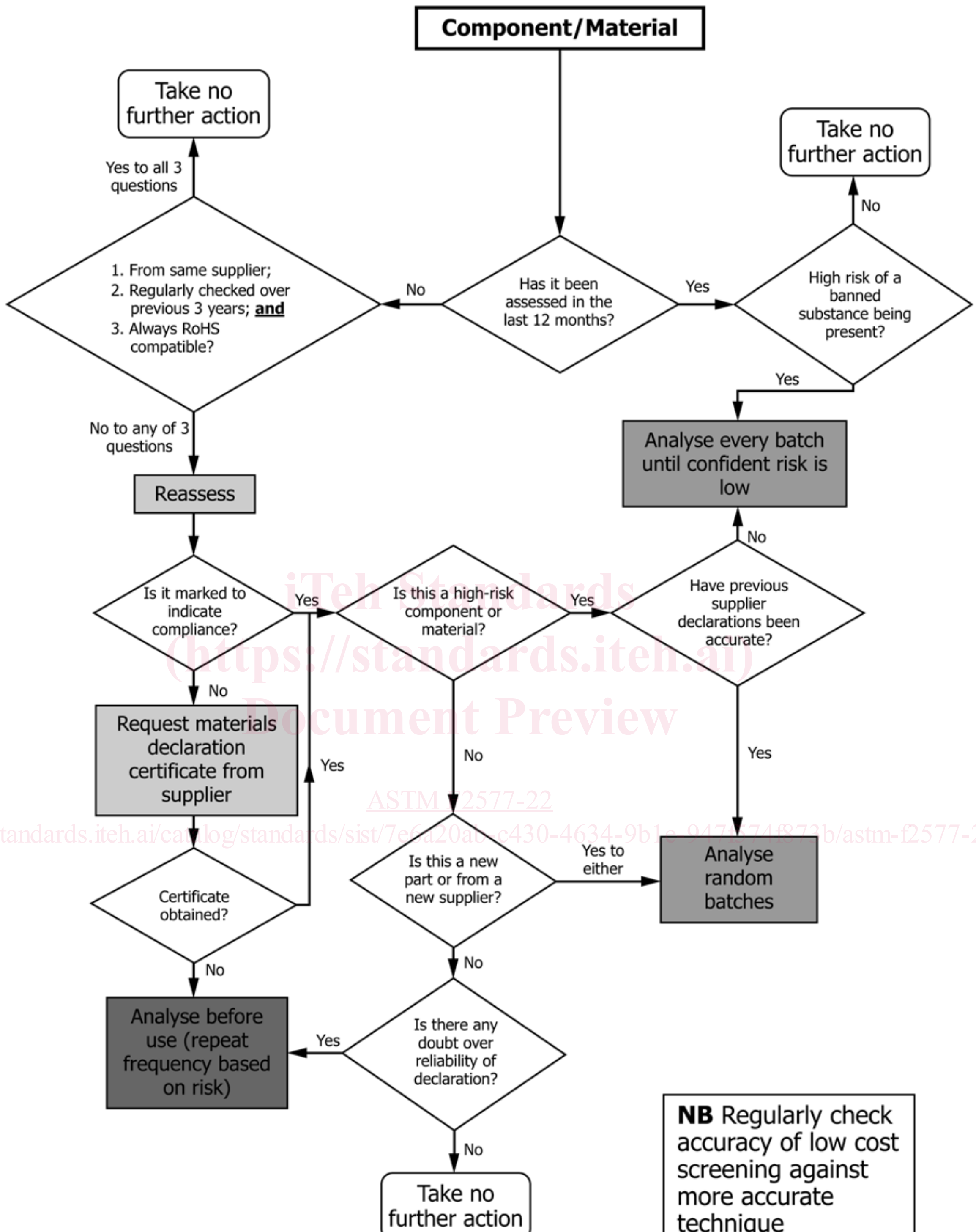

FIG. X1.2 Flow Chart from the United Kingdom Department of Transportation and Industry (DTI) for Use as a Guide to Help Clarify the Compliance Process with Regard to RoHS Directive Requirements *(DTI ROHS Regulations, Government Guidance Notes* **(4)***. Reproduced by permission from the United Kingdom Department of Transportation and Industry (DTI).)*