Designation: ~~F2577 – 14~~ F2577 – 22

Standard Guide for ~~Assessment of Materials and Products for Declarable Substances~~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 ~~This guide is limited to the referenced European Union directives. Other regions, countries, states or local municipalities may adopt these or similar regulations.~~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~~ safety, health, and ~~health~~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.*

[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 ~~March 1, 2014~~Oct. 1, 2022. Published ~~April 2014~~November 2022. Originally approved in 2006. Last previous edition approved in ~~2006~~2014 as F2577~~–06.~~–14. DOI: ~~10.1520/F2577-14.~~10.1520/F2577-22.

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 ~~*Other Documents:*~~ *IEC Standards:*

~~DTI ROHS Regulations Government Guidance Notes, November 2005, SI 2005 No. 2748~~[33]

~~European Commission Decision 2005/618/EC~~IEC 62321-8:2017 ~~Commission Decision of 18 August 2005 amending Directive 2002/95/EC of the European Parliament and of the Council for the purpose of establishing the maximum concentration values for certain hazardous substances in electrical and electronic equipment~~Determination of certain substances in electrotechnical products Part 8: Determination of specific phthalates in polymer materials by mass spectrometry

~~European Union Directive 2011/65/EU (recast of 2002/95/EC) on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment~~[5]

~~European Union Directive 2012/19/EU~~IEC 62474:2012 ~~on Waste Electrical and Electronic Equipment~~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 Terms and definitions related to declarable substances in materials may be found in Terminology F2576.~~

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

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]

~~3.2 Terms and definitions in the guide not found in Terminology F2576 may be found in a common dictionary or other reference documents such as the ASTM Dictionary of Engineering Science & Technology.~~[7]

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

[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.

[5] ~~Official Journal of the European Union, L174/88 08.06.2011.~~ The boldface numbers in parentheses refer to a list of references at the end of this standard.

[6] ~~Official Journal of the European Union, L 197/1 04.07.2012.~~

[3] ~~DTI RoHS Regulations, Government Guidance Notes, November 2005, SI 2005 No. 2748," p. 23. Reproduced by permission from the United Kingdom Department of Transportation and Industry (DTI).~~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] ~~Official Journal of the European Union, L 214/65, 19.8.2005; notified under document number C(2005) 3143.~~ Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

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 ~~Due to~~Because of requirements being placed on concentrations of declarable substances within (or on) materials, assessing conformance of products has become a complex, ~~time-consuming~~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 ~~in order~~ 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 ~~posterior~~posteriori~~i~~* 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 ~~as a means~~ 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 ~~Assessment of plastics~~ For some regulations and directives, a clear *de minimis*~~for presence of declarable substances is more complex than assessment of metals and~~ threshold has been defined for a substance or group of substances. In the absence of a prescribed ~~*alloys, since*~~*de minimis,* ~~the possible ingredients are comparatively much more numerous in plastic manufacture.~~ 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 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 ~~where~~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~~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.~~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 ~~must~~shall be declared. It is important to determine the basis to which the limits apply ~~in order~~ to ~~properly~~ assess ~~conformance.~~ conformance properly. For example, the limits may apply to an entire product or they may apply to each material within the ~~product~~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 ~~Certificates of~~

~~Analysis~~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 ~~each and~~ every certificate obtained from suppliers via repetition of testing, it is good practice to ~~periodically~~ confirm material ~~data.~~data periodically.

5.6 Assess the material or product for conformance to requirements based upon *a priori* and *a posteriori* ~~*information.*~~ information. The concentrations of any declarable substances in materials or products are compared to the limits set by the requirements ~~in order~~ 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~~products.

~~**6. Case Studies**~~

~~6.1 A finished aluminum part is to be evaluated for conformance to the requirements of European Union Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS). It was established that the part would be incorporated into a finished electrical product to be sold on the European market after the effective date of the RoHS Directive and the finished product fits the description of electrical products to be regulated per the RoHS Directive and European Union Directive 2011/65/EU (recast of 2002/95/EC) on Waste Electrical and Electronic Equipment (WEEE).~~

~~6.1.1 The chemical requirements of the RoHS Directive are given in European Commission Decision 2005/618/EC as follows: the Maximum Concentration Value (MCV) for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) is 0.1% by weight per homogeneous material and the MCV for cadmium is 0.01% by weight per homogeneous material. Per the Annex of the RoHS Directive, aluminum is exempt from the restriction on lead and is allowed to contain up to 0.4% by weight lead. No other exemption was applicable to the aluminum part.~~

~~6.1.2 *A priori* knowledge of aluminum and its method of manufacture were used to evaluate the part. Aluminum is not flammable under normal conditions, so there is a low probability that flame retardants such as PBB or PBDE were part of the formulation. Furthermore, the temperature of a typical aluminum smelter is maintained at 920°C – 980°C at which organic substances such as PBB or PBDE are decomposed and become volatile gases, so organic substances will not remain in the finished aluminum metal. While metal alloys may contain the element chromium, the chromium within the metal is in the metallic state with an atomic valence of zero. With regard to metals, hexavalent chromium is not found within the metal but may be found on the exterior surfaces in the form of a chromate conversion coating. Hexavalent chromium may also be found in coatings such as paint and plastic since hexavalent chromium compounds have been employed as pigments in such materials. Lead may be found in some free machining aluminum alloys at levels above the RoHS MCV. Cadmium can be found in aluminum as a contaminant, but is added intentionally in only two alloys (2021 and 4013) which are not commonly produced at this time. Mercury is volatile and is not likely to be found in aluminum or its alloys, though there are some formulations used as sacrificial anodes containing mercury at 0.03 to 0.06% Small concentrations of mercury in aluminum will cause the aluminum to be rapidly oxidized and converted into aluminum oxide, so a piece of solid aluminum is unlikely to contain more than 0.1% mercury.~~

~~6.1.3 Application of *a priori* knowledge of aluminum and its manufacture results in a preliminary assessment concerning the presence of certain substances. The preliminary assessment of the aluminum part to the requirements of RoHS points to which substances should be measured and which should not: there is a good probability that cadmium or lead may be present within the aluminum part; there is a low probability that mercury may be present and there is a possibility that hexavalent chromium may be found on the surface of the part. Conversely, there is low probability that PBB or PBDE are present in the aluminum. Completing the evaluation of the aluminum part to RoHS requirements requires *a posteriori* knowledge, or knowledge that is based on measurement. At some point in the life of the aluminum metal, testing would be required to quantify the concentrations of lead, cadmium, mercury and hexavalent chromium associated with the aluminum. Information on the lead and cadmium content, as well as total chromium, may be available in the form of a Certificate of Analysis generated by the producer or by an independent laboratory. If such a document is not available or the available information requires verification, testing of the part is required to evaluate conformance to requirements. Aluminum Association specifications require that aluminum producers maintain a surveillance program for mercury so that production is monitored on a periodic (quarterly within North America) basis to ensure that mercury has not been introduced into any of the production processes. The test method(s) applied to the aluminum part should be designed specifically for analysis of the substances on or within aluminum or aluminum alloys; in other words, both the~~

substance sought and the material to be analyzed should be included in the scope of the test method. If a standard method does not exist, it is incumbent upon the laboratory to demonstrate that the method employed is valid for analysis of the substance in (or on) the specific material tested.

6.1.4 Validation of a method can be accomplished through analysis of a reference material, preferably a certified reference material with traceability to SI units, using the same method of analysis as is used on the unknown sample. The reference material used for validation of the method shall be of the same or similar composition of the unknown sample; for example, the reference material used to validate the analysis of aluminum or its alloys for a substance shall be covered by the scope of the test method for aluminum and its alloys and shall also contain a known concentration of the substance to be measured.

NOTE 4—A reference material to be used for validation of a test method should not also be used for calibration of the instrument.

NOTE 5—The instrument used for analysis of the sample is not as important as demonstration that the instrument is capable of analyzing substances in specific materials; such capability may be demonstrated through validation of the test method.

6.2 A red piece of polyvinyl chloride (PVC) is to be evaluated for conformance to the requirements of the RoHS Directive. It was established that the PVC sample represented material which would be incorporated into a finished electronic product to be sold on the European market after the effective date of the RoHS Directive. The finished product fits the description of electronic products to be regulated per the RoHS and WEEE Directives.

6.2.1 After review of the directive, it was determined no exemptions were applicable to the red PVC sample.

6.2.2 Application of *a priori* knowledge of PVC and its manufacture results in a preliminary risk assessment concerning the presence of certain substances. The sample was colored red, indicating that a colorant was used in the formulation. Pigments red in color which have been used in plastic manufacture include lead, cadmium, mercury and hexavalent chromium compounds. Lead and cadmium have also been used as stabilizers in PVC formulations. Various PBDE and PBB have been used as flame retardants in PVC, but the risk of PBB being present is low since PBB production was phased out long ago.

6.2.3 The producer of the blended PVC material is in a good position to assess the risk of certain substances being present in the plastic, since they know the formula and thus the ingredients used to manufacture the material. The use of *a priori* knowledge by the producer may result in an accurate assessment and virtually eliminate the need to test the material for declarable substances. The producer knows whether cadmium, lead, mercury, hexavalent chromium, PBB or PBDE is part of the formula and they know whether recycled material was added to any production batch. If the producer does not use any of the declarable substances in the formula, the only risk of those substances being present in the finished plastic may be from addition of recycled material or from contaminants. If no recycled material was added to the batch, the only risk of declarable substances being present in concentrations above allowable limits would be if contaminants were present. The PVC manufacturer can further minimize the need for testing ingredients by requesting information on declarable substances from ingredient producers.

6.2.4 The producers of the ingredients are in the best position to assess the risk of certain substances being present in those ingredients. Those producers may apply *a priori* and *a posteriori* knowledge to assess the presence of declarable substances. For example, ethylene and chlorine are used to manufacture ethylene dichloride (ECM) which is further processed to manufacture vinyl chloride monomer (VCM). VCM is polymerized to make pure PVC. Nowhere in the process are lead, cadmium, mercury, hexavalent chromium, PBB or PBDE used or created and it is unlikely any of those substances could be incorporated as contaminants. A calcium carbonate producer can eliminate the possibility that PBB or PBDE are present, since the product is either mined as calcium carbonate or precipitated as calcium carbonate from carbonation of lime, which is also mined. The calcium carbonate producer probably can not eliminate the possibility that lead, cadmium, mercury or hexavalent chromium are present using *a priori* knowledge, so testing would likely be required to determine concentrations of those substances. The test method(s) applied to the calcium carbonate should be designed specifically for analysis of the substances within calcium carbonate; in other words, both the substance sought and the material to be analyzed should be included in the scope of the test method. If a standard method does not exist, it is incumbent upon the laboratory to demonstrate that the method employed is valid for analysis of the substance in the specific material tested.

NOTE 6—Compounds containing lead, cadmium, mercury, hexavalent chromium or PBDE may be added to PVC in a blending stage after the production of pure PVC, but are not involved in the pure PVC production process.

NOTE 7—Materials which are mined are at risk of containing contaminants, particularly metallic elements or compounds. Conversely, materials which are mined are not likely to contain manmade materials in significant concentrations.

6.2.5 The blended PVC manufacturer may use test results or declared amounts from the suppliers to calculate declarable substance

~~concentrations expected in the final product based on the concentration of the ingredients and the yield of the product. For example, the concentration of lead in the finished product may be calculated as shown in Table 1. The PVC producer could additionally or alternatively analyze the raw materials received from the supplier as part of quality assurance procedures; frequency of such testing could be determined by the producer or could be as agreed with clients. A determination of frequency of testing could be based in part on past history of transactions with the supplier such that as confidence is gained with supplied data the frequency of testing could diminish. In general, new materials or materials from a new supplier should be tested more frequently than those with an established level of confidence based on data history. A further means of quality assurance would be for the PVC manufacturer, interim or final user to test the finished product for declarable substances.~~

~~NOTE 8—It may be difficult to validate test results for many finished plastic blends due to the vast number of possible formulations and thus potential biases of measurements. Care shall be taken in selection of reference materials used to validate results of testing plastic blends.~~

6. Keywords

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

~~APPENDIX~~APPENDIXES

(Nonmandatory Information)

X1. FLOW CHARTS

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