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Standard Guide for Assessment of Materials and Products for Declarable Substances¹

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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 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*²

[F2576 Terminology Relating to Declarable Substances in Materials](#)

2.2 *Other Documents:*

[DTI ROHS Regulations Government Guidance Notes, November 2005, SI 2005 No. 2748](#)³

[European Commission Decision 2005/618/EC 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](#)⁴

[European Union Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in Electrical and](#)

[Electronic Equipment](#)⁵

[European Union Directive 2002/96/EC on Waste Electrical and Electronic Equipment](#)⁶

3. Terminology

3.1 Terms and definitions related to declarable substances in materials may be found in Terminology [F2576](#).

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 Due to requirements being placed on concentrations of 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.

4.2 *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.

4.3 *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.

4.4 Test methods can be used as a means to verify and provide information related to substances within materials. At

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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 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).

⁴ Official Journal of the European Union, L 214/65, 19.8.2005; notified under document number C(2005) 3143.

⁵ Official Journal of the European Union, L 37/19, 13.2.2003.

⁶ Official Journal of the European Union, L 37/24, 13.2.2003.

⁷ Sponsored by ASTM Committee E02 on Terminology; available from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; ASTM Stock Number: DEF00.

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.

4.5 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.

4.6 Assessment of plastics for presence of declarable substances is more complex than assessment of metals and alloys, since the possible ingredients are comparatively much more numerous in plastic manufacture.

4.7 This guide includes a general process and case studies in order to provide guidance and to distinguish where *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 must be declared. It is important to determine the basis to which the limits apply in order to properly assess conformance. For example, the limits may apply to an entire product or they may apply to each material within the product

NOTE 1—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.

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 2—*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 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.

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 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 3—*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. 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 2002/96/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 Exemptions to RoHS Directive requirements include the use of decaBDE (a PBDE congener) and other brominated flame retardants not classified as PBB or PBDE and not otherwise regulated by European law. No other 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