



Designation: F99 – 07(Reapproved 2011)

## Standard Guide for Writing a Specification for Flexible Barrier Rollstock Materials<sup>1</sup>

This standard is issued under the fixed designation F99; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

### 1. Scope

1.1 This guide defines the requirements and considerations for flexible barrier materials.

1.2 This guide addresses some critical printing requirements for flexible barrier materials.

1.3 Guidance is provided on specification requirements and considerations for flexible barrier materials intended to be purchased as rollstock.

1.4 If the flexible barrier material is intended to be purchased in the form of a pre-made sterile barrier system, Guide F2559 should be referenced.

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

### 2. Referenced Documents

2.1 *ASTM Standards:*<sup>2</sup>

D4321 Test Method for Package Yield of Plastic Film

F17 Terminology Relating to Flexible Barrier Packaging

F88 Test Method for Seal Strength of Flexible Barrier Materials

F2097 Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

F2203 Test Method for Linear Measurement Using Precision Steel Rule

F2250 Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials

F2251 Test Method for Thickness Measurement of Flexible Packaging Material

F2475 Guide for Biocompatibility Evaluation of Medical Device Packaging Materials

F2559 Guide for Writing a Specification for Sterilizable Peel Pouches

2.2 *TAPPI Standard:*<sup>3</sup>

T 437 Dirt in Paper and Paperboard

2.3 *FDA Document:*<sup>4</sup>

21 CFR 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

### 3. Terminology

3.1 *Definitions*—For definitions and terms used in this guide, see Terminology F17.

3.2 *Definitions:*

3.2.1 *carbon particles*—carbon particles are bits of parent material (resin) that have seen excessive heat in processing.

3.2.2 *gels*—small particles of resin with higher-than-average molecular weight and that appear as small, hard glassy particles. Gels are not foreign material and are inherent to many polymer-based materials.

3.2.3 *specification*—an explicit set of requirements to be satisfied by a material, product, system, or service. Examples of specifications include, but are not limited to, requirements for; physical, mechanical, or chemical properties, and safety, quality, or performance criteria. A specification identifies the test methods for determining whether each of the requirements is satisfied.

3.2.4 *telescoping*—transverse slipping of successive winds of a roll of material so that the edge is conical rather than flat.

### 4. Summary

4.1 This standard provides guidance for writing a specification for flexible barrier materials. Materials, method of manufacture, physical properties, performance requirements, dimensioning, appearance, printing, and labeling are all issues that need to be addressed in a flexible barrier material specification.

<sup>1</sup> This guide is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

Current edition approved Aug. 1, 2011. Published November 2011. Originally approved in 1976. Last previous edition approved in 2007 as F99 – 07. DOI: 10.1520/F0099-07R11.

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

<sup>3</sup> Available from Technical Association of the Pulp and Paper Industry (TAPPI), 15 Technology Parkway South, Norcross, GA 30092, <http://www.tappi.org>.

<sup>4</sup> Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, <http://www.fda.gov>.