



CCE COORDINATION BULLETIN 2005-2

Applicability of 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces (18-nn), and 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces (20-nn) in Processing Equipment

Purpose: This guideline applies to the evaluation of rubber, rubber-like and plastic materials in equipment to be covered by a 3-A Symbol.

Application: The following guidance shall be used by the CCE when performing TPV evaluations of equipment that utilizes rubber, rubber-like or plastic material(s). This guidance is effective immediately upon receipt and shall be used until revoked or included in an up-date of the TPV Manual. This bulletin supercedes CCE Coordination Bulletin 2004-1, dated March 1, 2004.

1. Identify the rubber, rubber-like and plastic material(s) used and for which components of the equipment, the materials are utilized by questioning the Fabricator or from notations on the drawings.
2. Verify against the materials section of the applicable Standard. Remember, if the item isn't listed as one of the applications, it is not allowed.
3. Verify against purchase orders or materials certification that the materials specified in the drawings are the materials that are purchased and that there have not been any substitutions.
4. If the plastics materials are listed on the previously issued Partial List of Acceptable Plastic Materials; or the rubber and rubber-like or plastic material(s) display a 3-A Symbol on the packaging material, make this notation on your TPV report as acceptable and continue with the TPV evaluation.
5. For Rubber, Rubber-Like and Plastic Material(s) not covered by Item 4 above, request documentation from the Fabricator demonstrating conformance to the Standards.
6. The documentation shall be provided by the supplier, signed by a responsible official with that company, bear the trade name of the material as shown on drawings and purchase

orders, and the appropriate declarations as shown below. Review of individual material test data is not necessary; however, verification of records for consistency shall be conducted.

- a. For rubber and rubber-like material(s), the documentation shall clearly indicate conformance with 21 CFR 177.2600 or the FDA Inventory of Effective Premarket Notifications for Food Contact Substances (<http://www.cfsan.fda.gov/~dms/opa-fcn.html>) and conformance to the *3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces, Number 18-nn* and the material conforms to class (x) of the standard.
- b. For plastic material(s), the documentation must clearly indicate conformance with the appropriate 21 CFR citation within parts 170-199 or the FDA Inventory of Effective Premarket Notifications for Food Contact Substances (<http://www.cfsan.fda.gov/~dms/opa-fcn.html>) and conformance to *3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces, Number 20-nn*. Verify against 21 CFR that the citations are correct and there are no disqualifying provisions.

Note: The CFR can be accessed at www.gpoaccess.gov/cfr/index.html.

When all of these steps can be answered affirmatively, the materials can be determined to be in conformance and the TPV Report can be marked as satisfactory. If any of these steps cannot be answered in the affirmative, the TPV Report is to be marked unsatisfactory and the TPV evaluation fails.

