Attachment # 2

Federal Register - 21 CFR, Part 121
(pgs. 8509 - 12, September 12, 1961)

Subpart F - Food Additives Resulting From Contact with Containers of Equipment and Food Additives Otherwise Effecting Food

ADHESIVES

The Commission of Food and Drugs having evaluated the data submitted in petitions filed by:

Monsanto Company
812 Monsanto Avenue
Springfield, Massachusetts

and other relevent material has concluded that the following regulation should issue with respect to food additive resulting from the use of adhesives as components of articles intended for use in packaging, transporting, or holding food. Under the prescribed conditions of safe usage, substances approved for use in adhesives are not expected to become components of food in any significant amount. Therefore pursuant to the provisions of the Federal Food, Drug and Cosmetic Act (sec. 409 (c) (1), 72 Stat. 1786; 21 U.S.C. 348 (c) (1) and under the authority delegated to the Commissioner by the Secretary of Health, Education and Welfare (25 FR 8625) the food additive regulations (21 CFR Part 121) are amended by adding to subpart F the following prescribed conditions:

a) Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

   1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section subject to any prescribed limitations:

      i) In dry foods - the quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice

      ii) In fatty and aqueous foods

         (a) The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limit of good manufacturing practice.

PCB-ARCH-EXT0375587

(b) Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation

(c) To assure safe usage of adhesives the label of the finished adhesive container shall bear, in addition to any other information required by the act, the statement "Food-packaging Adhesive."

(d) Subject to any limitations prescribed in this section and in any other regulation promulgated under section 409 of the act which prescribes safe conditions for use for substances that may be employed as constituents for adhesives, the optimal substances used in the formulation of adhesives may include the following:

(1) Substances generally recognized as safe for use in food or food packaging

(2) Substances permitted for use in adhesives by prior sanction or approval and employed under the specific conditions of use prescribed by such sanction or approval.

(3) Flavoring substances permitted for use in food by regulations in this part, provided that such flavoring substances are volatilized from the adhesives during the packaging fabrication process.

(4) Color additives approved for use in food.

(5) Substances permitted for use in adhesives by other regulations in this subpart and substances named in this subparagraph. Provided however, that any substance named in this subparagraph and covered by a specific regulation in this subpart must meet any specifications by in such regulation. Any substance not covered by a specific regulation in this subpart shall meet the specifications, if any, set forth in an order that has been issued extending the effective date of the statute for use of the substance as a component of articles that contain food

PCB-ARCH-EXT0375588

Components of Adhesives

(chlorinated biphenyl not listed)

dated August 31, 1961

Leo P. Larick
Commissioner of Food & Drugs

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