change would result in higher procurement costs, longer delivery times, and that small business cannot provide the proper maintenance and repair. SBA cannot accept these statements as fact; it is our position that the small business community is capable of providing an adequate distribution system, maintaining delivery schedules, and providing the repair and maintenance as required.

Other comments have indicated that certain phrases contained in the proposed rule should be deleted. It was felt that the last sentence, ". . . distributor or dealer selling in substantial *quantities* to local commercial customers and be *located within the local trading area* of the Federal purchasing office awarding the contract or in the location of where the supplies or services are to be delivered;" may be subject in part to misinterpretation and, also, may be unduly restrictive to small business. (Emphasis added.)

The firms commenting felt that the phrase "selling in *substantial* quantities" cannot be quantitatively defined and, left in the current broad terms, may be subject to misinterpretation by contracting officials. (Emphasis added.)

The last part of the sentence "and be located with the local trading," also is difficult to define and, additionally, should not be a factor in determining a firm's size status.

SBA concurs in these two comments and will eliminate the last sentence of the proposed rule.

PART 121—SMALL BUSINESS SIZE STANDARDS

Accordingly, pursuant to authority contained in Section 5(b)(6) of the Small Business Act, as amended, 15 U.S.C. 634, Schedule D of Part 121, Chapter I of Title 13, Code of Federal regulations is amended to read as follows:

In § 121.3–8, paragraph (c)(2)(i) is revised to read:

§ 121.3–8 Definition of small business for Government procurements.

* * * * *

(c) Nonmanufacturing. * * *

* * * * *

(2)(i) In the case of government procurement reserved for small businesses, such nonmanufacturer furnishes in the performance of the contract the products of a small business manufacturer or producer, which products are manufactured or produced in the United States: Provided, however, If the procurement has an anticipated value of less than $10,000 and is subject to, and is actually processed under "small purchase procedures" as defined in the Federal Acquisition Regulation or, pending issuance thereof by the Office of Federal Procurement Policy, in the Defense Acquisition Regulation (DAR), Federal Procurement Regulation (FPR), and the National Aeronautics and Space Administration Procurement Regulation (NASAPR), as applicable, such nonmanufacturer may furnish any domestically produced or manufactured product.

* * * * *

Dated: January 7, 1980.

A. Vernon Weaver,

Administrator.

[FR Doc. 80–1257 Filed 1–14–80; 8:45 am]

BILLING CODE 6025–01–M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 175

[Docket No. 79F–0310]

Indirect Food Additives: Adhesive Coatings and Components; 2-Sulfoethyl Methacrylate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The food additive regulations are amended to provide for the use of 2-sulfoethyl methacrylate as a component of adhesives used in articles intended for food contact. This action is based on a petition filed by the Dow Chemical Co.

DATES: Effective January 15, 1980; objections by February 14, 1980.

ADDRESS: Written objections to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Bureau of Foods (HFF–334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: A notice published in the **Federal Register** of September 7, 1979 (44 FR 52339) announced that a food additive petition (FAP 9B3448) had been filed by the Dow Chemical Co., Midland, MI 48640, proposing that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of 2-sulfoethyl methacrylate as a component of copolymers used as adhesives in articles intended for food-contact applications.

Having evaluated data in the petition and other relevant material, the Food and Drug Administration concludes that § 175.105 should be amended to include the petitioned food additive as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 175 is amended in § 175.105 by alphabetically inserting in the list of substances in paragraph (c)(5) a new item to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	*Limitations*
* * * * *	
2-sulfoethyl methacrylate (CAS Registry No. 10595–80–9).	For use at levels not to exceed 2 percent by weight of the dry adhesive.
* * * * *	

Any person who will be adversely affected by the foregoing regulation may at any time on or before February 14, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective January 15, 1980.

[Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))]

Dated: January 8, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-1158 Filed 1-14-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 177

[Docket Nos. 75F-0284, 76F-0013, 76F-0341, 77F-0368, 78F-0060, 78F-0149]

Indirect Food Additives: Polymers; High-Temperature Laminates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is amending the food additive regulations to provide for safe use of certain laminated food containers capable of withstanding heat sterilization. A number of petitioners have requested the amendments. The present regulation will also incorporate certain materials which have been previously authorized in existing regulations or by letter.

DATES: Effective January 15, 1980; objections by February 14, 1980.

ADDRESSES: Objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:

Introduction

This document responds to six food additive petitions (FAP) requesting amendment of the indirect food additive regulations to provide for use of certain laminated containers for packaging food under heat sterilization conditions where the temperature does not exceed 250° F.

Five petitions requested use of containers composed of layers consisting of polyolefin and polyethylene phthalate polymers and aluminum foil bonded together by certain polyurethane laminating adhesives. Notices of filing for these five petitions were published in the **Federal Register** as follows:

1. FAP 6B3131, Reynolds Metal Co., 6601 Broad St., Richmond, VA 23261. (40 FR 52076; Nov. 7, 1975).

2. FAP 6B3152, Ludlow Corp., Flexible Packaging Division, Mount Vernon, OH (formerly a division of Continental Diversified Industries). (41 FR 5861; Feb. 10, 1976).

3. FAP 6B3195, DRG Flexible Packaging, Ltd., Filwood Rd., Fishponds, Bristol BS16 3RY England. (43 FR 14737; Apr. 7, 1978).

4. FAP 6B3223, Toyo Seikan Kaisha, Ltd., 3-1 Uchisaiwaicho 1-Chome, Chiyoda-Ku, Tokyo 100, Japan. (41 FR 38802; Sept. 13, 1976).

5. FAP 7B3297, DeSoto, Inc., 1700 S. Mount Prospect Rd., Des Plaines, IL 60018. (43 FR 5891; Feb. 10, 1978).

This document is a partial response to these petitions pending assurance of "no reasonable expectation" of migration of 2,4-diaminotoluene to food. 2,4-Diaminotoluene is a hydrolysis product of these polyurethane adhesives and of toluene diissocyanate, an adhesive component. A recent National Cancer Institute (NCI) report indicates that 2,4-diaminotoluene is a moderately high-potency carcinogen (NCI (1979), Carcinogenesis Technical Report Series No. 162, Bethesda, MD). The authorization for use of these urethane adhesives is being deferred pending evaluation of the potential for 2,4-diaminotoluene to migrate into food. Further action concerning the polyurethane adhesives will be the subject of a separate **Federal Register** document.

A notice published in the **Federal Register** of June 23, 1978 (43 FR 27236), announced that food additive petition 8B3376 (FAP 8B3376), filed by Emser Industries, Inc., Teaneck, NJ, requested amendment of the regulations to provide for the use of nylon 12 laminate, produced by laminating the condensate of *omega*-laurolactam to aluminum foil, as a component of food containers to be used under heat sterilization conditions. The safe use of this laminate is provided for in this document.

Description and Definitions

The ensuing regulation provides for the safe use of a class of packaging materials having a number of unique features. These articles are layered constructions, typically bonded with adhesives. Containers can be fabricated having a wide range of shapes, flexibility, and thickness as well as different numbers of layers. High-temperature laminates have been shown to be functional for processing and packaging food at retorting temperatures (250° F). The flexible form of such a high temperature laminated container is commonly referred to as a retortable pouch because it is heat processed in "retort" equipment.

Food-contact articles produced in accordance with paragraph (c) of § 177.1390 (21 CFR 177.1390) are composite structures where the food-contact layer is usually a polyolefin resin such as a polypropylene copolymer or a polyethylene-polyisobutylene blend. The food-contact layer is typically bonded to aluminum foil by an adhesive. There may be an optional outer layer of polyester to provide extra strength. The laminates included in paragraph (d) of § 177.1390 are composite structures where the food-contact layer, nylon 12, is fused to aluminum foil.

The aluminum foil precludes the diffusion into food of any components outside it, including adhesives, and thus serves as a functional barrier to these materials.

For retortable pouches, two pieces of laminate would be heat-sealed together on three sides to from a pouch. After if is filled with food, the pouch would be heat sealed on the fourth side. Subsequently, the filled containers would be processed at a temperature not to exceed 250° F (121° C) for a time necessary to ensure sterilization. The sterilized contents are then shelf-stable for periods of at least several months at room temperature. In this way, these laminated packaging materials are functionally similar to metal cans. Proir to use, the consumer would typically reheat the food in the container before serving.

History and Background

Retortable pouches have been under development in the United States for the last two decades. They have been in commerical use abroad (most notably in Japan and in several European countries) for up to 8 years.

Certain types of laminated containers have been sanctioned by FDA in letters to individual manufacturers because they employ materials in compliance with existing regulations. One group includes the "boil-in-bags" and "hot-fill and hold" container intended for use at or below 212° F (100° C). FDA considered the polymeric food-contact films (the inner liners) of these types of articles to act as functional barriers to the adhesives used to laminate the films. FDA recently discovered, however, that adhesive components can migrate through food-contact films when laminate containers are used in the thermal processing of foods, and has since required verification that the food-contact film serves as a functional barrier. A second group employs materials until now authorized under § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300), which may also function as adhesives for use in containers not to be heated above 250° F. Provision for the use of these

materials has been incorporated into § 177.1390(c)(2) below. The knowledge that adhesive components migrate through the food-contact layer when subjected to thermal processing and thus become food additives dictates the need for the present regulation.

The purpose of the present regulation is to prescribe the materials for construction and conditions of use of this class of food-contact articles intended for processing at temperatures no greater than 250° F and holding of shelf-stable foods. The requirements of the new § 177.1390 will supersede any previous advisory opinion letters for such articles. Consideration of other similar packaging materials for use at or below 212° F will be the subject of a future regulation.

Special Considerations

Volatile substances. A number of low-molecular-weight volatile substances, such as solvents, are routinely used in the manufacture of the food-contact films as well as the adhesives used for laminating the films. Although no explicit mention is made of quantitative limits for these volatile substances in § 177.1390(c)(4)(ii), all high-temperature laminate articles covered by the regulation are to be manufactured under conditions of good manufacturing practice in accordance with paragraph (a) of § 174.5 *General provisions applicable to indirect food additives* (21 CFR 174.5), so that such volatile materials will be removed from the article to the greatest extent possible in keeping with good manufacturing practice before filling it with food.

GRAS substances. Generally Recognized as Safe (GRAS) substances may be used as components of the laminated structures. Although these substances are not explicitly listed in § 177.1390, § 174.5 provides for the use of appropriate GRAS substances as well as appropriate indirect additives in the manufacture of laminate structures, provided: (1) these substances are used in accordance with good manufacturing practice; (2) they are used only in amounts necessary to accomplish the intended effect; and (3) they are used in accordance with prescribed limitations of any relevant indirect food additive regulation.

Package integrity and thermal processing. Food packaged in retortable containers is shelf-stable at ambient temperatures for extended periods similar to periods for foods packaged in the traditional can. Thus, it is necessary to take proper precautions to ensure adequate thermal processing of foods packaged in retortable containers and to ensure adequate package intergrity to maintain the hermetic seal. Food processors using retortable containers should refer to FDA's regulations—21 CFR Parts 108, 110, 113, and 114—relating to proper thermal processing and good manufacturing practice (GMP) for canning operations. Processors of meat and poultry containing products should contact the Food Safety and Quality Service of the United States Department of Agriculture (USDA) to determine their requirements regarding retortable container thermal processing and package integrity.

The American Society for Testing and Materials (F–2 Flexible Barrier Materials Committee) has begun to develop test methods and specifications for retortable pouches and related packages. This effort and the USDA standards follow from the substantial work on retortable pouch integrity by the U.S. Army Natick Research and Development Command. As data on package integrity are developed, FDA will reassess the need to proposed separate GMP regulations for high-temperature laminates.

Miscellaneous. The 250° F (121°C) processing temperature is assumed to have a maximum possible error of ±5° F (±2.8° C).

FDA has evaluated the data in the above-listed petitions and other relevant material and concludes that Part 177 (21 CFR Part 177) should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 177 is amended as follows:

1. By adding a new § 177.1390, to read as follows:

§ 177.1390 High-temperature laminates.

(a) The high-temperature laminates identified in this section may be safely used for food contact at temperatures not exceeding 250° F (121° C) unless otherwise specified. These articles are layered constructions that are optionally bonded with adhesives. The interior (food-contact) layer(s) may be separated from the exterior layer(s) by a functional barrier, such as aluminum foil. Upon review of the physical properties of a particular construction, the Food and Drug Administration may consider other layers to serve as functional barriers. This regulation is not intended to limit these constructions as to shape, degree of flexibility, thickness, or number of layers. These layers may be laminated, extruded, coextruded, or fused.

(b) When containers subject to this regulation undergo heat sterilization to produce shelf-stable foods, certain control measures (in addition to the food additive requirements in paragraphs (c) and (d) of this section) are necessary to ensure proper food sterilization and package integrity. Refer to Parts 108, 110, 113, and 114 of this chapter for details.

(c) Subject to the provisions of this paragraph, food-contact articles produced from high-temperature laminates may be safely used to package all nonalcoholic [1] food types.

(1) *Polymeric films/layers.* Films or layers not separated from food by a functional barrier must meet the following requirements:

(i) Films/layers may consist of the following:

(A) Polyolefin resins complying with item 2.2 or 3.2 of the table in § 177.1520(c).

(B) Polymeric resin blends formulated from a base polymer complying with item 2.2 or 3.2 of the table in § 177.1520(c) blended with no more than 10 percent by weight of a copolymer of ethylene and vinyl acetate complying with § 177.1350.

(C) Polymeric resin blends formulated from a base polymer complying with item 2.2 or 3.2 of the table in § 177.1520(c) blended with no more than 38 percent by weight of a homopolymer of isobutylene complying with § 177.1420(a)(1).

(D) Polyethylene phthalate resins complying with § 177.1630(e)(4) (i) and (ii).

(E) Polymeric resins that comply with an applicable regulation in this chapter which permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(ii) Adjuvants used in these layers must comply with an applicable regulation that permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(2) *Adhesives.* The use of adhesives in these constructions is optional. Adhesives separated from food by a layer that does not serve as a functional barrier may be composed of maleic anhydride adduct of polypropylene complying with § 175.300 of this chapter. Other substances complying with § 175.105 of this chapter may be used as components of adhesives used in these constructions provided they are separated from the interior (food-

[1] With respect to FDA regulations for indirect additives, the term "nonalcoholic" refers to foods containing less than 1.0 percent ethanol. The Bureau of Alcohol, Tobacco, and Firearms may consider foods of greater than 0.5 percent ethanol by volume to be taxable.

contact) layer(s) by a functional barrier as discussed under paragraph (a) of this section.

(3) *Test specifications.* These specifications apply only to materials on the food-contact side of a functional barrier, if present. All tests must be performed on containers made under production conditions. Laminated structures submitted to extraction procedures must maintain complete structural integrity (particularly with regard to delamination) throughout the test.

(i) *Nonvolatile extractives.* The container interior (food-contact side) shall be extracted with deionized distilled water at 250° F (121° C) for 2 hours. The chloroform-soluble fraction of the total nonvolatile extractives shall not exceed 0.01 milligram per square inch (0.0016 milligram per square centimeter) as determined by a method available upon request from the Food and Drug Administration.[2]

(ii) *Volatiles.* Volatile substances employed in the manufacture of high-temperature laminates must be removed to the greatest extent possible in keeping with good manufacturing practice prescribed in § 174.5(a) of this chapter.

(d) Nylon 12/aluminum foil high-temperature laminates: Subject to the provisions of this paragraph, containers constructed of nylon 12 laminated to aluminum foil may be safely used at temperatures no greater than 250° F (121° C) in contact with all food types except those containing more than 8 percent alcohol.

(1) The container is constructed of aluminum foil to which nylon 12 film is fused. Prior to fusing the nylon 12, the aluminum foil may be optionally precoated with a coating complying with § 175.300 of this chapter.

(2) Nylon 12 resin complying with § 177.1500 and having an average thickness not to exceed 0.0016 inch (41 microns) may be used as the food-contact surface of the container.

(3) Container test specifications. On exposure to distilled water at 250° F (121° C) for 2 hours, extractives from the food-contact side of the nylon 12 multilayered construction shall not exceed 0.05 milligram per square inch (0.0078 milligram per square centimeter) as total nonvolatile extractives.

2. By amending § 177.1500(b) by revising the conditions of use for the entry for Nylon 12 in the table, to read as follows:

§ 177.1500 Nylon resins.

* * * * *

(b) * * *

Nylon resins	Specific gravity	Melting point (°F)	Solubility in boiling 4.2*N* HCl	Maximum extractable fraction as selected solvents (expressed in percent by weight of resin)			
				Water	95 pct ethyl alcohol	Ethyl acetate	Benzene
*	*	*	*	*	*	*	*
9. Nylon 12 resins for use only in food-contact films having an average thickness not to exceed 0.0016 inch intended for use in contact with nonalcoholic food under the conditions of use A (sterilization not to exceed 30 minutes at a temperature not to exceed 250°F), and B through H of table 2 of § 176.170(c) of this chapter, except as provided in § 177.1390(d).	* * *	* * *	* * *	* * *	* * *	* * *	* * *
*	*	*	*	*	*	*	*

Any person who will be adversely affected by the foregoing regulation may at any time on or before February 14, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective January 15, 1980.

(Sec. 409(c)(1), 72 Stat. 1986 (21 U.S.C. 348(c)(1)))

Dated: January 3, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–1157 Filed 1–14–80; 8:45 am]

BILLING CODE 4110–03–M

[2] Address: Bureau of Foods, Petitions Control Branch (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[Docket No. 78–207; RM 3208 & 3209]

Radio Broadcast Service; TV Assignment to Boca Raton, Hollywood and West Palm Beach, Fla.

AGENCY: Federal Communications Commission.

ACTION: Report and Order.

SUMMARY: This action assigns a television channel to Hollywood, Florida, to provide for a first local television service. Changes are also made at Boca Raton, Florida, and West Palm Beach, Florida. These changes are designed to resolve a short-spacing conflict between applicants for new stations at Miami and West Palm Beach. A previously proposed change at Miami, Florida, was not necessary.

DATE: Effective February 22, 1980.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.