

THE REGULATORY CONTROL OF PLASTIC FOOD-PACKAGING

MATERIALS IN THE UNITED STATES

by

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The Food and Drug Administration has great respect for the excellent work of the Pan American Health Organization in combating disease and promoting the health of the people of the Western Hemisphere. We are indeed honored to be invited to participate in this 5th Annual Seminar on Food and Drug Control and to discuss with you our regulatory control of plastic materials intended for use in contact with food.

We currently exercise control over such plastics under the provisions of the 1958 Food Additives Amendment to the U.S. Federal Food, Drug, and Cosmetic Act. This food protection amendment, together with the Pesticide Chemicals Amendment of 1954 and the Color Additives Amendment of 1960, greatly strengthened our law to help us better protect the consumer against unsafe substances in his food supply. These three amendments have been well characterized as pretesting, preclearance amendments. In general, they require proof of safety and government clearance before any new chemicals can be added to food.

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For presentation at the World Health Organization/Pan American Health Organization 5th Annual Seminar on Food and Drug Control for Central America and Panama, May 26-31, 1969, Managua, Nicaragua.

Although the term "food additive" is of relatively recent origin, the addition of chemicals to food is a very old practice which probably began when man first learned to preserve meat by putting salt on it. Since that time, the science of food chemistry has made tremendous progress, particularly since the turn of the century. Today, a great many chemical substances are being safely employed to make food more attractive, better tasting, and more economical. The growing, processing, and packaging of food so that it can be transported for thousands of miles and remain in good condition for months or even years is truly one of the outstanding achievements of our time. However, during Congressional hearings in the middle and late 1950's, a consensus of expert opinion established that a number of these chemicals being used in foods had not been adequately tested for safety. Although most manufacturers made tests and consulted with FDA concerning the safety of their products, not all of them did nor were they required to do so. It became increasingly clear that our law had to be changed to prevent the addition to food of unsafe chemicals.

Under the Federal Food, Drug, and Cosmetic Act of 1938, as it was prior to September 1958, FDA could not prevent the use of a chemical additive simply because it was questionable or had not been adequately tested. It was necessary to be able to prove the chemical additive was poisonous or deleterious. This was not difficult to prove in the case of chemicals that cause immediate or acute illness; however, scientists were concerned with the long-term effects of exposure to minute amounts of chemicals over a

period of years or even a life time, and proving a chemical to be poisonous or deleterious under these circumstances may be very difficult. Often several years of feeding tests on different kinds of animals may be required to determine the chronic effects resulting from the addition of small amounts of chemicals to the diet.

From 1950 to 1958 U. S. Congressional Committees intensively studied the problem of how to protect the consumer from inadequately tested food additives. The culmination of these studies was the enactment of the Food Additives Amendment in September 1958. This Amendment was one of the pioneer statutes recognizing the need for control of potential environmental hazards. It provides for the control of food additives, whether they are added directly and intentionally to food to accomplish a particular technical effect or whether they become a component of food indirectly through migration from food-packaging materials or other sources such as food-processing equipment and machinery.

For purposes of the Food Additives Amendment, the term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, subject to certain specified exemptions. The amendment specifically includes "any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use." Under

the amendment the term "food additive" does not include the following exempted substances: (1) substances recognized by appropriately qualified experts as being safe for their intended use, (2) substances used in accordance with a sanction or approval granted prior to September 6, 1958 under the Federal Food, Drug, and Cosmetic Act, the Meat Inspection Act, or the Poultry Products Inspection Act; however, such exemptions are limited to the specific uses for which the sanctions were given, (3) pesticide chemicals used under the provisions of the Pesticide Chemicals Amendment to the Act, and (4) color additives used under the provisions of the Color Additives Amendment to the Act. The law specifies that a food additive is deemed to be unsafe unless its use is subject to an exemption or unless it is used in accordance with a food additive regulation prescribing safe conditions of use. It establishes a procedure whereby a person wishing to use a food additive may petition for a regulation for such use by demonstrating that it is, in fact, safe for its intended use.

When the Food Additives Amendment was passed in 1958, plastics and other materials intended for use in contact with food became a matter of increased interest to the Food and Drug Administration. Basic materials required study to determine whether they would migrate to food in sufficient quantity to be hazardous to the consumer. Similar studies were also necessary on the adjuvants, such as stabilizers, plasticizers, etc., needed to make the basic materials functional. All had to be considered under the Act and their use as food additives required regulation prescribing safe conditions of use.

The following discussion will be limited to plastics and their adjuvants that have been regulated or otherwise permitted for use in contact with food under the provisions of our Food Additives Amendment. It provides a summary of materials under regulation. Complete details can be obtained by consulting the cited references which include information on any usage restrictions or other limitations considered necessary to assure safe use of the additives. These references refer to the appropriate section of the U. S. food additive regulations which are found under Title 21 of our Code of Federal Regulations.

In the ten years we have been regulating food additives, we have issued a number of regulations to provide for the use of many synthetic polymers and their adjuvants in contact with food. These regulations may be divided into three groups: those dealing with the basic synthetic polymer (Table 1); compositions containing synthetic polymers (Table 2), and adjuvant materials used with synthetic polymers (Table 3).

TABLE 1--SYNTHETIC POLYMERS REGULATED AS INDIRECT FOOD ADDITIVES

	(Reference)
Acrylamide-acrylic acid resins	121.2512
Acrylate ester copolymer coatings	121.2525
Acrylic and modified acrylic plastics, semirigid and rigid	121.2591
Chlorinated polyether resins	121.2581
1,4-Cyclohexylene dimethylene terephthalate and 1, 4-cyclohexylene dimethylene isophthalate copolymer	121.2533
Ethylene-acrylic acid	121.2564
Ethylene-ethyl acrylate copolymers	121.2554
Ethylene-methacrylic acid copolymers, ethylene- methacrylic acid-vinyl acetate copolymers, and their partial salts	121.2582
Ethylene-methyl acrylate copolymers	121.2528
Ethylene-vinyl acetate copolymers	121.2570
Fluorocarbon resins	121.2523
Hydroxyethyl cellulose, water insoluble film	121.2567
Isobutylene polymers	121.2590
4,4'-Isopropylidenediphenol-epichlorohydrin resins, minimum molecular weight 10,000	121.2579
4,4'-Isopropylidenediphenol-epichlorohydrin, thermosetting epoxy resins	121.2585
Melamine-formaldehyde resins in molded articles	121.2549
Nylon resins	121.2502
Olefin polymers	121.2501
Partial phosphoric acid esters of polyester resins	121.2601
Perfluorocarbon resins	121.2555
Phenolic resins in molded articles	121.2587

Table 1 (cont'd)

	(Reference)
Polycarbonate resins	121.2574
Poly(2,6-dimethyl-1,4-phenylene)oxide resins	121.2603
Polyester resins, cross-linked	121.2576
Polyethylene	121.2501
Polyethylene, chlorinated	121.2532
Polyethylene, oxidized	121.2517
Polyethylene resins, carboxy modified	121.2580
Polymer modifiers in semirigid and rigid polyvinyl chloride	121.2597
Poly(methylpentene)	121.2501
Polypropylene	121.2501
Polystyrene and rubber-modified polystyrene	121.2510
Polysulfide polymer-polyepoxy resins	121.2572
Polyurethane	121.2522
Polyvinyl alcohol film	121.2598
Polyvinylidene fluoride resins	121.2593
Styrene-divinylbenzene copolymers	121.2584
Urea-formaldehyde resins in molded articles	121.2595
Vinyl acetate-crotonic acid copolymers	121.2540
Vinyl chloride-ethylene copolymers	121.2609
Vinyl chloride-propylene copolymers	121.2521
Vinylidene chloride copolymer coatings for nylon film	121.2599
Vinylidene chloride copolymer coatings for polycarbonate film	121.2600
Vinyl chloride-lauryl vinyl ether copolymers	121.2608
Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins	121.2559

TABLE 2--MATERIALS CONTAINING SYNTHETIC POLYMERS REGULATED AS  
INDIRECT FOOD ADDITIVES

	(Reference)
Adhesives	121.2520
Cellophane	121.2507
Closures with sealing gaskets for food containers	121.2550
Components of paper and paperboard in contact with aqueous and fatty foods	121.2526
Components of paper and paperboard in contact with dry food	121.2571
Filters, resin-bonded	121.2536
Hot-melt strippable food coatings	121.2578
Lubricants with incidental food contact	121.2553
Packaging materials for use during the irradiation of prepackaged foods	121.2543
Polyethylene terephthalate film	121.2524
Pressure-sensitive adhesives	121.2577
Reinforced wax	121.2530
Resinous and polymeric coatings	121.2514
Resinous and polymeric coatings for polyolefin films	121.2569
Rubber articles intended for repeated use	121.2502
Surface lubricants used in the manufacture of metal articles	121.2531
Textiles and textile fibers	121.2535
Textryls	121.2545

TABLE 3--ADJUVANTS FOR SYNTHETIC POLYMERS. REGULATED AS  
INDIRECT FOOD ADDITIVES

	<u>(Reference)</u>
Adjuvant substances used in the manufacture of foamed polystyrene	121.2583
Antioxidants and/or stabilizers for polymers	121.2566
Antistatic and/or antifogging agent in food-packaging materials	121.2527
Emulsifiers and/or surface-active agents	121.2541
Emulsifiers used in the manufacture of coatings for paper and paperboard	121.2521
4-Hydroxymethyl-2,6-di- <u>tert</u> -butylphenol	121.2508
Octyltin stabilizers in polyvinyl chloride plastics	121.2602
Plasticizers for polymeric materials	121.2511
Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids	121.2605
Release agents	121.2509
Ultramarine blue	121.2563

In addition to these regulated additives, there are a number of synthetic polymers and their adjuvants that may be used in contact with food in accordance with sanctions or approvals granted prior to passage of the Food Additives Amendment. Section 121.2001 of the food additive regulations contains a partial listing of substances, including a number of synthetic polymer/adjuvants, that are prior sanctioned for use in the manufacture of food-packaging materials. In addition to substances listed in section 121.2001, FDA recognizes a prior sanction for all food-packaging applications for polyvinyl chloride basic resins that have a maximal volatility of not over 3.0 percent when heated for one hour at 105° C. and that have an inherent viscosity of not less than 0.35, as determined by ASDM D 1243-60, Method A. In addition Table 4 contains a list of other synthetic polymers for which prior sanctions have been granted for use as films for food-contact use.

TABLE 4--SYNTHETIC POLYMERS FOR WHICH PRIOR SANCTIONS HAVE BEEN  
GRANTED FOR USE AS FILMS

Acrylonitrile-butadiene-styrene copolymers

Butadiene-acrylonitrile copolymers

Cellulose acetate

Ethyl cellulose

Polyester-ethylene terephthalate and ethylene isophthalate

Polyethyl acrylate

Polymethyl acrylate

Polyvinyl chloride-acetate

↑ These all covered by  
Kelman article

There are also a few synthetic polymers that are generally recognized as safe for their intended use as listed in Section 121.101 of the food additive regulations. Table 5 contains the synthetic polymers in that list. The methyl cellulose and sodium carboxymethyl cellulose must be the grades specified for direct food use.

TABLE 5--SYNTHETIC POLYMERS GENERALLY RECOGNIZED AS SAFE FOR THE  
INTENDED PURPOSE

Direct Food Additives:

Methyl cellulose

Sodium carboxymethyl cellulose

Substances Migrating from Paper and Paperboard:

Cellulose acetate

Ethyl acrylate

Ethyl cellulose

Methyl acrylate

Section 121.2500 of the food additive regulations defines good manufacturing practice for additives regulated for food packaging use. This regulation includes <sup>the</sup> provision that substances used as components of food-contact articles shall be of a purity suitable for their intended use and further stipulates that regulated packaging materials shall not impart odor or taste to any food product such as to render it unfit for use within the meaning of the Act.

Basic polymers that are permitted for use in contact with food under the provisions of the Food Additives Amendment, may be mixed with each other provided there is no chemical reaction between the component of the mix. In such cases, the most restrictive use limitation applies to the mixture. For example, polyurethane resins are limited to use with dry bulk foods only, so mixtures containing these resins would be subject to the same limitation. The adjuvants, limited according to their regulations, may also be used in mixture with other basic polymers. Other adjuvants listed in the prior sanction list may also be mixed with regulated synthetic polymers.

*Detwiler principle*

Certain of the regulations -- most of those in Table 2 -- cover a wide variety of synthetic polymers. The appearance of the material in these regulations does not indicate safety for all uses, but only for those specified. For example, Section 121.2520 of the food additive regulations (Adhesives) is written to minimize the contact between food and adhesives. With such use restrictions, many components are listed in this

regulation as safe only because migration to food will be toxicologically insignificant. Similarly, some of the substances listed in certain other regulations have been established as safe only under the specified conditions.

As part of a continuing effort to improve administration of the provisions of the Food Additives Amendment, the Food and Drug Administration conducted a National Conference on Indirect Food Additives on February 13-14, 1968, in Washington, D. C. One of the objectives of the conference was to seek the advice of the scientific community on the adequacy and appropriateness of the Food and Drug Administration's scientific policies concerning control and regulation of the so-called "incidental additives" that become a component of food indirectly through migration from food-packaging materials or other sources such as food processing equipment and machinery. A major controversial issue discussed at that conference is whether all of the requirements of food additive petitions for indirect food additives are actually necessary. Many of the industries represented at that conference endorsed the opinion of Dr. John P. Frawley of Hercules, Inc., first expressed in a paper delivered before the American Chemical Society in New York on December 14, 1966, and reiterated on a number of occasions subsequently. Dr. Frawley holds that any substance (except pesticides, heavy metals, and carcinogens) which is suitable for use as a functional component in a food package or container, at a level of 0.2 percent or less, cannot become a component of food at an unsafe level and hence toxicology studies or migration studies need not be required.

Dr. Frawley contends that it is a waste of our scientific resources to utilize them on packaging problems in such cases because they can be of no possible health significance.

Although we have been unable to accept Dr. Frawley's proposal completely, we are presently considering proposing amendment of our food additive regulations to establish additional broad categories of substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food. Under the contemplated conditions of use, we would not expect these additional substances to become components of food in any toxicologically significant amounts. In this connection we are considering proposing amendment of our food additive regulations to permit substances (except carcinogens, heavy metals, and any other substances that have been demonstrated to produce toxic reactions when present at levels at 40 parts per million or less in the diet of men or animals) to be used under any one of the following conditions: (1) as components of food-contact articles, provided any substance so used contributes no more than 0.05 part per million of additives to the contacted food as determined by analysis of the food, or by appropriate extraction studies, or by calculations assuming 100 percent migration; (2) as components of articles intended for use in contact with dry foods with surfaces containing no free fat or oil, provided the finished food-contact surface contains no free oils not otherwise permitted for such use; (3) as components of articles intended for repeated use in contact with bulk quantities of food, provided the finished food-contact article is thoroughly cleansed prior to first use in contact

with food; (4) as components of defoaming agents employed prior to or during the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food; and (5) as components of food-packaging adhesives used under conditions precluding any significant migration of adhesive to food.

A preliminary draft of our proposal was sent early this month to representatives of the various industry trade associations which took part in our 1968 FDA-Industry Conference on Indirect Additives. We have asked these affected industries to express their views on our proposal which we believe would simplify and improve our indirect food additive regulatory process without in any way jeopardizing public safety.

There are, of course, still a number of synthetic polymers and synthetic polymer adjuvants that could be used in food-packaging applications which are not yet covered by our regulations. In addition, interest has been expressed in obtaining clearance for additional food-packaging uses for a number of the presently regulated synthetic polymers and their adjuvants. Last year we received an average of six new food additive petitions each month requesting regulations for food-packaging applications, mainly involving synthetic polymers and their adjuvants. Section 121.51 of the food additive regulations details the procedures to be followed in preparing such petitions. In this connection, I have available for distribution copies of our "FDA Guideline for Chemistry and Technology Requirements of Food Additive Petitions." These guidelines reflect our views with respect to the type of data and other information needed for

making an intelligent and informed evaluation of a food additive petition in the area of chemistry technology. These guidelines suggest ways to conduct extraction studies to determine what and how much of any indirect food additives can be expected to migrate from food-packaging materials and food-processing equipment to individual foods or classes of foods under the proposed conditions of use. We find that extraction or migration studies for plastics and other food-packaging materials are usually required to provide a sound basis for assessing the safety of their use. Before the toxicologist can give purposeful attention to the appraisal of the safety of any substance in food, it is essential that he know the nature and the amount of the substance expected to migrate to the food as a result of the proposed use. Without this information we are unable to comment regarding what additional toxicity studies, if any, may be necessary for the purpose of a petition. It is also necessary to consider the extent to which a new food-packaging material is likely to be used. As indicated in Table 6, polyethylene and cellophane presently account for approximately 80% of all food-packaging films used in the United States.

TABLE 6--MILLIONS OF POUNDS OF FOOD-PACKAGING FILM USED IN THE U.S.A.

	1966		1967		1968	
Polyethylene <sup>1</sup>	360	(47.3)	365	(46.9)	395	(47.6)
Cellophane <sup>1</sup>	296	(39.0)	285	(36.6)	280	(33.8)
Polyvinyl chloride <sup>2</sup>	28	( 3.7)	49	( 6.3)	63	( 7.6)
Polypropylene <sup>2</sup>	31.5	( 4.1)	35	( 4.5)	45.5	( 5.5)
Polyvinylidene chloride <sup>2</sup>	14	( 1.8)	14	( 1.8)	15.4	( 1.9)
Polystyrene <sup>2</sup>	7.7	( 1.0)	8.4	( 1.1)	9.1	( 1.1)
Polyester <sup>2</sup>	5.6	( 0.7)	5.6	( 0.7)	5.6	( 0.7)
Rubber hydrochloride <sup>2</sup>	10.5	( 1.4)	7	( 0.9)	4.9	( 0.6)
Cellulose acetate <sup>2</sup>	3.5	( 0.5)	3.5	( 0.5)	3.5	( 0.4)
All others <sup>2</sup> (including nylon, fluorocarbon, polyvinyl alcohol, polycarbonate, etc.)	3.5	( 0.5)	5.6	( 0.7)	7	( 0.8)
TOTAL	760.3	(100)	778.1	(100)	829	(100)

<sup>1</sup> Industry estimates as reported in Modern Packaging Encyclopedia (1968 Edition)

<sup>2</sup> Estimated maximum calculated at 70% total production for this type of film as reported in Modern Packaging Encyclopedia (1968 Edition)

In concluding my remarks, I would like to point out to you that there is no authority under the Food Additives Amendment for our individual "approval" of proprietary products. We have no control over the day-to-day formulation of proprietary products and the responsibility for compliance with the requirements of the Food Additives Amendment to our Act must in all cases fall upon the manufacturer. We do, however, routinely offer informal comment regarding the food additive status of constituents in formulations when we are furnished quantitative formulas.

Anyone desiring advisory assistance or information concerning the status of his products under the Federal Food, Drug, and Cosmetic Act is invited to contact the Bureau of Compliance, Division of Case Guidance, Food and Drug Administration, Consumer Protection and Environmental Health Service, Public Health Service, U. S. Department of Health, Education, and Welfare, Washington, D. C. 20204. Requests for such advisory opinions should give the essential facts and details of the inquiry, including, when applicable, a complete description of the product and its intended use.

If desired, interested parties may also obtain through our Bureau of

Compliance reprints of the food additive and other FDA regulations that are published in the FEDERAL REGISTER. If desired, we will also add their names to our mailing list so that they receive future reprints of changes to these regulations. There is no charge for this service.

In this brief and general discussion of our regulatory program, I have passed quickly over many important parts and will be glad to attempt to answer any questions you may have. In closing, I want to thank you again for your invitation to participate in the Seminar and for your attention.