

uplicate, shall be filed within the 48 hours with the district director at the Customs port of entry nearest the U.S. port of destination.

(f) Within 60 days after the date of mailing or personal delivery to a withdrawer of two copies of the consolidated report of all withdrawals under a given warehouse entry, the withdrawer shall sign the Certificate of Use on one copy of the report, return it to the district director together with a satisfactory documented reconciliation of all discrepancies, and file a duty-paid withdrawal for any of the fuel not properly accounted for. The other copy of the consolidated report shall be retained by the withdrawer. A Customs Form 7309 is not required with a duty-paid withdrawal, Customs Form 7505, filed in connection with the reconciliation. Oil import licenses shall be charged when appropriate.

(g) The certificate of use shall read as follows:

I hereby certify that the fuel indicated above, with the exceptions as noted, (1) was laden for use as supplies for aircraft operated by the United States, or (2) was laden aboard an aircraft registered in the United States and, as reported to us by the respective airline, actually engaged in foreign trade or trade between the United States and any of its possessions, or (3) was laden for use as supplies for an aircraft registered in any foreign country where trade by foreign aircraft is permitted, entitled to the reciprocal privileges as provided in section 309(d) of the Tariff Act of 1930, as amended (19 U.S.C. 1309(d)), and, as reported to us by the respective airlines, actually engaged in foreign trade or trade between the United States and any of its possessions, or (4) was laden aboard foreign military aircraft in accordance with item 841.20 of the Tariff Schedules of the United States (19 U.S.C. 1202), on the basis of reciprocity.

(h) The district director, upon written application, may extend the 60-day period for the filing of the documents and any deposit of duties required under paragraph (f) of this section, if the district director is satisfied that the withdrawer has been or will be prevented by circumstances beyond his control from filing the documents and depositing the duties within the 60-day period.

(i) For purposes of this section, a U.S.-registered aircraft chartered and operated by a foreign airline shall be deemed to be a foreign-registered aircraft. The country of registry (flag) of the aircraft shown on the Bonded Fuel Control Card, Customs Form 7309, shall be the country code of the foreign airline.

(Sec. 309, 46 Stat. 690, as amended; 19 U.S.C. 1309); R.S. 251, as amended, sec. 309, 46 Stat. 690, sec. 624, 46 Stat. 759; 19 U.S.C. 66, 1309, 1624.)

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Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart E—Prior-Sanctioned Food Ingredients

A proposal was published in the FEDERAL REGISTER of August 12, 1972 (37 FR 16407) to provide for regulation of prior-sanctioned ingredients by revising the title of subpart E of the food additive regulations and establishing general provisions applicable to prior-sanctioned ingredients.

Four comments were received in response to this proposal. All four comments were primarily concerned with the legality of regulating prior-sanctioned food ingredients and with providing procedural safeguards within the proposed regulation. Specific comments were that the exemption from food additive status of prior-sanctioned ingredients set forth in the Federal Food, Drug, and Cosmetic Act section 201(s) (4) cannot be changed as set forth in the proposal; that absence from listing under subpart E of 21 CFR part 121 cannot affect the prior-sanctioned status of food ingredients; that food packaging materials employing prior-sanctioned ingredients cannot be considered food under section 402(a) (1) of the act; and that procedural safeguards permitting opportunity to submit additional evidence of safety of prior-sanctioned ingredients before a proposal to change its status, and a 60-day comment period and opportunity for public hearing, should be included in the regulation for any proposed or final regulations generated from review of prior-sanctioned ingredients.

Having evaluated the comments and other relevant information, the Commissioner concludes as follows:

1. There is no merit to the argument that prior-sanctioned food ingredients are exempt from safety evaluation under the adulteration provisions of the act. Such ingredients are poisonous or definition of "food additive" under section 201(s) (4) of the act but are subject to all the requirements of section 402. Subpart E, as promulgated by this order, will incorporate the Commissioner's determinations with respect to the safety of prior-sanctioned ingredients in accordance with section 402 of the act.

2. Section 701(a) of the act is sufficient legal authority to permit promulgation of regulations determining the safety of prior-sanctioned direct and indirect food ingredients, including a finding that any such ingredients are poisonous or deleterious adulterants of food. Prior-

sanctioned ingredients used in food packaging which are in contact with food, and consequently may become an indirect adulterant of food, are not excluded from regulation under section 402 of the act.

3. Expansion of subpart E under part 121 is intended to provide a listing of all known prior-sanctioned food ingredients. Whether a food ingredient is used as a result of a determination that it is GRAS, or pursuant to a food additive regulation, or as a result of a prior sanction, the basis for such use should be a matter of public record. Accordingly, the Food and Drug Administration will publish in this subpart all known prior-sanctioned direct and indirect food ingredients and any subsequent limitations placed upon the use of the ingredient when scientific data justifies such limitations. It is acknowledged that not all known prior-sanctions are presently listed in this subpart. This will be remedied by publication of the prior-sanction status of those ingredients supplied in response to the Food and Drug Administration's request for information on prior sanctions (35 FR 5810) and as requests for affirmation of the safety of prior-sanctioned ingredients are acted upon.

4. The respondents requesting procedural safeguards to permit submission of additional evidence of safety prior to any Food and Drug Administration proposal to place limitations on the use of a prior-sanctioned ingredient, is not feasible. The Food and Drug Administration does not have a file of all users of prior-sanctioned ingredients. It is suggested that anyone who has significant safety information on a prior-sanctioned ingredient submit such evidence to the Food and Drug Administration now, or as it becomes available to them, or as they request affirmation of the safety of the prior-sanctioned ingredients. Publication of a proposal to place limitations on the use of a prior-sanctioned ingredient will, in any event, provide for submission of such information.

The request for other procedural safeguards, including statements that interested persons may comment within 60 days upon publication of any proposal to change the regulatory status of a prior-sanctioned ingredient and adversely affected persons may have a right to request a hearing on any consequent final order, are governed by the provisions of the act and the Administrative Procedure Act. The Commissioner is presently considering a revision of all Food and Drug Administration procedural regulations, which will deal with these matters with respect to all regulations issued under section 701(a) of the act.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat.

1055 and 72 Stat. 1784-88, as amended; 21 U.S.C. 321(a); 348, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), subpart E of part 121 is amended as follows:

1. The title of subpart E is revised to read, "Subpart E—Prior-Sanctioned Food Ingredients."

2. Section 121.2001 is redesignated as § 121.2005 and a new § 121.2000 is added to read as follows:

§ 121.2000 General.

(a) An ingredient whose use in food or food packaging is subject to a prior sanction or approval within the meaning of section 201(a)(4) of the act is exempt from classification as a food additive. The Commissioner will publish in this subpart all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by evidence to show that it falls within section 201(a)(4) of the act.

(b) Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the act, the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.

Effective date.—This regulation shall become effective June 14, 1973.

(Secs. 201(a), 409, 701(a), 52 Stat. 1055 and 72 Stat. 1784-1788, as amended; 21 U.S.C. 321(a), 348, 371(a).)

Dated May 10, 1973.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 73-9621 Filed 5-14-73; 8:45 am]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

RESINOUS AND POLYMERIC COATINGS

The Commissioner of Food and Drugs, having evaluated data in a petition (FAP 2B2812) filed by FPG Industries, Inc., P.O. Box 312, Delaware, Ohio 43015, and other relevant material, concludes that the food additive regulations should be amended as set forth below to provide for the additional safe use of the butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers specified in the regulations as a repair surface for coatings intended to contact food.

Therefore, pursuant to provisions of

the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1788; 21 U.S.C. 348(c)(1)) and under authority delegated to the Commissioner (21 CFR 2.120), part 121 (21 CFR part 121) as amended in § 121.2514 in paragraph (b) (3) (xx) by revising the item beginning "Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers" to read as follows:

§ 121.2514 Resinous and polymeric coatings.

- (b) * * *
- (3) * * *
- (xx) * * *

Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings or surface repair coatings that are applied by electrodeposition to metal substrates as follows:

1. In coatings that are intended for contact with food containing no more than 8 percent alcohol under conditions of use D, E, F, or G described in table 2 of § 121.2514 (d).

2. In surface repair coatings, provided that the repaired surface area in contact with food does not exceed 3 percent of the surface area of the container part being repaired.

Any person who will be adversely affected by the foregoing order may at any time on or before June 14, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date.—This order shall become effective May 15, 1973.

(Sec. 409(c)(1), 72 Stat. 1788; 21 U.S.C. 348(c)(1).)

Dated May 8, 1973.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 73-9542 Filed 5-14-73; 8:45 am]

SUBCHAPTER F—REGULATIONS UNDER SPECIFIC ACTS OF CONGRESS OTHER THAN THE FEDERAL FOOD, DRUG, AND COSMETIC ACT
PART 295—REGULATIONS UNDER THE POISON PREVENTION PACKAGING ACT OF 1970

Modification of the Testing Procedure for Special Packaging

In the FEDERAL REGISTER of January 15, 1973 (38 FR 1510), the Commissioner of Food and Drugs proposed to modify the testing procedure for special packaging (21 CFR 295.10(a)(3)) to change the definition of a unit packaging test failure to any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower. At that time, the maximum number of individual units constituting a test failure was more than 5.

Three comments were received in response to the proposal. A pharmaceutical manufacturer and a pharmaceutical trade association support the proposal and a city government agency does not.

The city government agency fears that the modification will reduce the degree of child protection provided by special packaging because although the amount of substance which would produce serious injury or illness prevails in establishing the number of units constituting a test failure, determining this amount for all children is difficult due to varying factors such as age and medical history.

The Commissioner, however, previously acknowledged that variables exist in establishing the amount of substance which would produce serious injury or illness. Accordingly, § 295.10(a)(3) (21 CFR 295.10) specifies that the determination of such amount shall be based on a 25-pound child. This weight represents the average 2-year-old child, the age most prone to accidental ingestions.

The present maximum test failure level of 5 was established to provide the packaging industry with parameters within which to develop unit packaging, but it has been found to be unnecessarily restrictive and has thus tended to stifle industry initiative in this area. This is undesirable since unit packaging has the potential for being an effective form of child protection packaging for many applications, particularly in the drug field. Having considered the comments, the Commissioner concludes that the proposed modification will not reduce or compromise the child protection properties of special unit packaging. The ultimately controlling factor in determining the test failure level in the case of unit packaging remains the number of individual units which constitute the