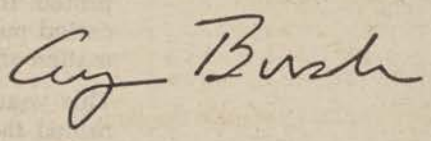
In 1938, the Congress passed a joint resolution (52 Stat. 148, 36 U.S.C. 150) requesting the President to issue an annual proclamation declaring April to be Cancer Control Month.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim the month of April 1991 as Cancer Control Month. I invite the Governors of the fifty States and the Commonwealth of Puerto Rico, and the appropriate officials of all other areas under the American flag, to issue similar proclamations. I also ask health care professionals, insurance companies, the communications and food industries, community groups, and individual citizens to join in continuing the progress made in fighting cancer.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of April, in the year of our Lord nineteen hundred and ninety-one, and of the Independence of the United States of America the two hundred and fifteenth.



[FR Doc 91-9023
Filed 4-12-91; 1:51 pm]
Billing code 3195-01-M

Rules and Regulations

Federal Register
Vol. 56, No. 73
Tuesday, April 16, 1991

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 317

Retention of Senior Executive Service Provisions

AGENCY: Office of Personnel Management.

ACTION: Interim rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing interim regulations on procedures for electing Senior Executive Service (SES) benefits by career SES members appointed to positions at Executive Level V or higher Under Public Law 101–335, additional individuals are now entitled to the election; and the law provides that certain individuals may make an election on a retroactive basis.

DATES: The interim regulations set forth below are effective on April 16, 1991. Written comments will be considered if received no later than June 17, 1991.

ADDRESSES: Send or deliver written comments to the Assistant Director, Office of Executive and Management Policy, HRDG, room 6R48, Office of Personnel Management, 1900 E Street NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Neal Harwood at 202–606–1610 (FTS 266–1610).

SUPPLEMENTARY INFORMATION: Under the Civil Service Reform Act of 1978 (Pub. L. 95–454), career Senior Executive Service (SES) members who received Presidential appointments with Senate confirmation at level V of the Executive Schedule or higher without a break in service were entitled to elect to retain certain SES benefits. These benefits included SES pay, annual and sick leave coverage, and eligibility for performance awards and Presidential rank awards. (5 U.S.C. 3392(c).)

Section 7 of Public Law 101–335 of July 17, 1990, extended this election right to certain other career SES members, irrespective of whether the appointment was by the President with Senate confirmation. The new law allows career SES members appointed without a break in service to Executive Schedule positions in the executive branch (or positions the rate of basic pay for which is fixed by statute at a rate equal to one of the levels of the Executive Schedule) on or after November 1, 1986, to make an election of the SES benefits, if they did not previously have an election right under their current appointment, effective the date of the appointment.

OPM is issuing regulations at 5 CFR part 317 to implement the provisions of Public Law 101–335. On the matter of individuals who can make a retroactive election, the question has arisen whether the individuals would be eligible for performance awards for years prior to the election. For example, if an individual who was appointed in November 1986 makes his election in May 1991, would the individual be eligible to receive on a retroactive basis performance awards for 1987, 1988, 1989, and 1990?

Under the regulations, if an individual elects performance awards, the awards could not be paid on a retroactive basis. Section 5384 of title 5 of the United States Code provides that to be eligible to receive a performance award, an individual must have been under the SES performance appraisal system for the period for which the award is being given and received at least a fully successful rating under subchapter II of chapter 43 of title 5, United States Code. In this case, the individual would not have been under the performance appraisal system for the earlier periods; and it is not possible to know in fact what the individual's rating would have been or what award he or she would have received at that time. An individual could receive an award in 1991, however, following an election as long as the minimum annual appraisal period was met.

Waiver of Notice of Proposed Rulemaking

In order to provide that any individual who is entitled to make an election under these regulations will be able to obtain all benefits for the 1991 period, including SES performance award eligibility, I find that good cause exists to waive the general notice of proposed rulemaking and to make these regulations effective in less than 30 days.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under Section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it will only affect Government employees who are members of the Senior Executive Service.

List of Subjects in 5 CFR Part 317

Government employees.

U.S. Office of Personnel Management.
Constance Berry Newman,
Director.

Accordingly OPM is amending 5 CFR Part 317 as follows:

PART 317—EMPLOYMENT IN THE SENIOR EXECUTIVE SERVICE

1. The authority citation for part 317 continues to read as follows:

Authority: 5 U.S.C. 3392, 3393, 3393a, 3395, 3397, 3593, and 3595.

2. Under subpart H, the heading for the subpart is revised, § 317.801(a) is revised, and § 317.801(d) is added to read as follows:

Subpart H—Retention of SES Provisions

§ 317.801 Retention of SES provisions.

(a) *Coverage.* This subpart applies to—

(1) A career appointee in the SES appointed at any time by the President to a civilian position in the executive branch with the advice and consent of the Senate at a rate of basic pay which is equal to or greater than the rate payable for Executive Level V; or

(2) A career appointee in the SES who is not covered under paragraph (a)(1) of this section and who was appointed on or after November 1, 1986, to a civilian position in the executive branch which is covered by the Executive Schedule, or the rate of basic pay for which is fixed by statute at a rate equal to one of the levels of the Executive Schedule.

* * * * *

(d) *Retroactive election.* (1) This paragraph applies to any individual who:

(i) Was serving on July 17, 1990, in a civilian position in the executive branch that was not in the SES and satisfies the conditions in paragraph (a)(2) of this section;

(ii) Has served continuously in such position since July 17, 1990;

(iii) Was an SES career appointee immediately before having been so appointed; and

(iv) Was not, under the individual's current appointment, previously eligible to make an election under 5 U.S.C. 3392(c).

(2) An individual covered by this paragraph shall make an election within 60 days of the effective date of these regulations which, if any, provisions under paragraph (b) of this section the individual wishes to retain. The election shall be effective as of the date of appointment to the position described in paragraph (d)(1) of this section.

(i) If basic pay is elected, the appointee is entitled to any difference between what the appointee's pay would have been under the SES pay provisions and the pay the appointee received since the date of appointment.

(ii) If leave coverage is elected, the appointee shall be credited with annual or sick leave earned since the appointment without regard to any ceiling on annual leave. Any time that would have been charged to annual leave or sick leave during the period, and which was not previously charged, shall be deducted to arrive at the appointee's current leave balance.

(iii) If performance awards or Presidential rank awards are elected, the appointee may first receive those awards approved after the election.

[FR Doc. 91-8912 Filed 4-15-91; 8:45 am]
BILLING CODE 6325-01-M

5 CFR Part 532

Prevailing Rate Systems

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing an interim regulation to define Pembina County, North Dakota, as an area of application to the Grand Forks, North Dakota, nonappropriated fund (NAF) Federal Wage System wage area.

DATES: Interim rule effective April 16, 1991; comments must be received on or before May 16, 1991.

ADDRESSES: Send or deliver comments to Phyllis G. Foley, Chief, Wage Systems Division, Room 7H30, Personnel Systems and Oversight Group, Office of Personnel Management, Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Gary Hacker (202) 606-2848.

SUPPLEMENTARY INFORMATION: Pembina County, North Dakota, is currently undefined for NAF pay setting purposes. The Air Force recently established three NAF crafts and trades positions at Cavalier Air Force Station, which is located in Pembina County. The three employees occupying the positions have been paid in the interim from the Grand Forks, North Dakota, NAF wage schedule. Pembina County has fewer than 26 wage employees subject to the NAF wage system; therefore, it does not meet the regulatory criteria contained in § 532.239 of title 5, Code of Federal Regulations, for establishment as a separate wage area. There are currently two wage areas, Grand Forks and Ward, that cover counties in North Dakota; however, Grand Forks is substantially closer than Ward to Pembina County. We find that Pembina County meets the criteria to be included in the Grand Forks wage area. The Federal Prevailing Rate Advisory Committee reviewed the request and unanimously recommended approval.

Under § 532.231(a)(1) of title 5, Code of Federal Regulations, the Office of Personnel Management is authorized to define the boundaries of wage and survey areas. The department of Defense is the lead agency for all NAF surveys and is making the request that OPM define Pembina County.

Pursuant to sections 553 (b)(3)(B) and (d)(3) of title 5, United States Code, I find that good cause exists for waiving the general notice of proposed rulemaking and for making these regulations effective in less than 30 days. The three positions are currently filled and out of administrative necessity the employees are already being paid from the Grand Forks wage schedule. The regulations are effective on April 16, 1991.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they would affect only Federal employees and Federal agencies.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Government employees, Wages.

U.S. Office of Personnel Management.

Constance Berry Newman,

Director.

Accordingly, OPM is amending part 532 of title 5 of the Code of Federal Regulations as follows:

PART 532—PREVAILING RATE SYSTEMS

1. The authority for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; Section 532.707 also issued under 5 U.S.C. 552, Freedom of Information Act, Pub. L. 92-502.

2. Appendix D to subpart B is amended by revising the wage area listing for Grand Forks, North Dakota, to read as follows:

Appendix D to Subpart B of Part 532—Nationwide Schedule of Nonappropriated Fund Regular Wage Surveys

* * * * *

North Dakota

Grand Forks

Survey area

North Dakota:
Grand Forks

Area of application. Survey area plus:

North Dakota:

Cass
Cavalier
Pembina
Steele

* * * * *

FR Doc. 91-8913 Filed 4-15-91; 8:45 am]
BILLING CODE 6325-01-M

FEDERAL TRADE COMMISSION

16 CFR Part 305

Rules for Using Energy Cost and Consumption Information Used in Labeling and Advertising of Consumer Appliances; Ranges of Comparability for Clothes Washers

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission amends its Appliance Labeling Rule by revising the ranges of comparability used on required labels for clothes washers.

Under the rule, each required label on a covered appliance must show a range, or scale, indicating the range of energy costs or efficiencies for all models of a

size or capacity comparable to the labeled model. This notice publishes the new range figures, which, under §§ 305.10, 305.11 and 305.14 of the rule, must be used on labels on clothes washers manufactured on and after July 15, 1991, and in advertising of clothes washers beginning July 15, 1991. Properly labeled clothes washers manufactured prior to the effective date need not be relabeled.

EFFECTIVE DATE: July 15, 1991.

FOR FURTHER INFORMATION CONTACT: James Mills, Attorney, (202) 326–3035, Division of Enforcement, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: On November 19, 1979, the Commission issued a final rule,[1] pursuant to section 324 of the Energy Policy and Conservation Act of 1975,[2] covering certain appliance categories, including clothes washers. The rule requires that energy costs and related information be disclosed on labels and in retail sales catalogs for all clothes washers presently manufactured. Certain point-of-sale promotional materials must disclose the availability of energy usage information. If a clothes washer is advertised in a catalog from which it may be purchased by cash, charge account or credit terms, then the range of estimated annual energy costs for the product must be included on each page of the catalog that lists the product. The required disclosures and all claims concerning energy consumption made in writing or in broadcast advertisements must be based on the results of test procedures developed by the Department of Energy, which are referenced in the rule.

Section 305.8(b) of the rule requires manufacturers, after filing an initial report, to report annually by specified dates for each product type.[3] Because the costs for the various types of energy change yearly, and because manufacturers regularly add new models to their lines, improve existing models and drop others, the data base from which the ranges of comparability are calculated is constantly changing.

To keep the required information in line with these changes, the Commission is empowered, under § 305.10 of the rule, to publish new ranges (but not more often than annually) if an analysis of the new data indicates that the upper or lower limits of the ranges have changed by more than 15%.

The new figures for the estimated annual costs of operation for clothes washers, which were calculated using the 1991 representative average energy cost for electricity (8.24 cents per kilowatt-hour) and natural gas (60.54 cents per therm) published by DOE on January 30, 1991,[4] have been submitted and have been analyzed by the Commission. New ranges based upon them are herewith published.

In consideration of the foregoing, the Commission amends appendix F of its Appliance Labeling Rule by publishing the following ranges of comparability for use in the labeling and advertising of clothes washers beginning July 15, 1991.

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR part 305 is amended as follows:

PART 305—[AMENDED]

1. The authority citation for part 305 continues to read as follows:

Authority: Sec. 324 of the Energy Policy and Conservation Act (Pub. L. 94–163) (1975), as amended by the National Energy Conservation Policy Act, (Pub. L. 95–619) (1978), the National Appliance Energy Conservation Act, (Pub. L. 100–12) (1987), and the National Appliance Energy Conservation Amendments of 1988, (Pub. L. 100–357) (1988), 42 U.S.C. 6294; sec. 553 of the Administrative Procedure Act, 5 U.S.C. 553.

2. In appendix F, Paragraph 1 and the introductory text in Paragraph 2 are revised to read as follows:

Appendices to Part 305

* * * * *

Appendix F—Clothes Washers

1. Range Information: "Compact" includes all household clothes washers with a tub capacity of less than 1.6 cu. ft. or 13 gallons of water.

"Standard" includes all household clothes washers with a tub capacity of 1.6 cu. ft. or 13 gallons of water or more.

Ranges of comparability	Ranges of estimated yearly energy costs			
	Electrically heated water		Natural gas heated water	
	Low	High	Low	High
Compact	$50.00	$95.00	$21.00	$37.00
Standard	22.00	150.00	10.00	55.00

2. *Yearly Cost Information:* Estimates on the scales are based on a national average electric rate of 8.24¢ per kilowatt hour, a national average natural gas rate of 60.54¢ per therm, and eight loads of clothes per week.

* * * * *

Donald S. Clark,

Secretary.

[FR Doc. 91–8885 Filed 4–15–91; 8:45 am]

BILLING CODE 6750–01–M

[1] 44 FR 66466, 16 CFR 305.

[2] Public Law 94–163, 89 Stat. 871 (Dec. 22, 1975).

[3] Reports for clothes washers are due by March 1.

[4] 56 FR 3455 (see correction at 56 FR 5455 (Feb. 11, 1991)). The Commission published these figures on March 5, 1991, at 56 FR 9123 (see correction at 56 FR 11589 (March 19, 1991)).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 87F-0361]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 1,6-hexanediol; 1,4-cyclohexane dimethanol; α-hydro-ω-hydroxypoly(oxy-1,4-butanediyl; methyl oxirane polymer with oxirane; and methyl oxirane polymer with oxirane, ether with 1,2,3-propanetriol as reactants; and tetrakis[methylene(2,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)]methane as an optional adjuvant in the production of polyurethane resins for use in contact with dry bulk food. This action responds to a petition filed by The Dow Chemical Co.

DATES: Effective April 16, 1991; written objections and requests for a hearing by May 16, 1991.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 23, 1987 (52 FR 48577), FDA announced that a food additive petition (FAP 7B4038) had been filed by The Dow Chemical Co., Midland, MI 48674, proposing that § 177.1680 *Polyurethane resins* (21 CFR 177.1680) be amended to provide for the safe use of 1,6-hexanediol; 1,4-cyclohexane dimethanol; α-hydro-ω-hydroxypoly(oxy-1,4-butanediyl); methyl oxirane polymer

with oxirane; and methyl oxirane polymer with 1,2,3-propanetriol as reactants, and tetrakis[methylene(2,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)]methane as an optional adjuvant in the production of polyurethane resins for use in contact with dry bulk food.

This document amends the nomenclature for the reactant described as methyl oxirane polymer with 1,2,3-propanetriol in the filing notice. The agency finds that a more appropriate nomenclature for this reactant is methyl oxirane polymer with oxirane, either with 1,2,3-propanetriol.

FDA, in its evaluation of the safety of the polyurethane resins, reviewed the safety of the reactants and the optional adjuvant, the starting materials used to manufacture the reactants and adjuvant, the byproducts of the reactants, and the impurities that may be present in the reactants. The agency is not aware of any data that show that 1,6-hexanediol; 1,4 cyclohexane dimethanol; α-hydro-ω-hydroxypoly(oxy-1,4-butanediyl); methyl oxirane polymer with oxirane; methyl oxirane polymer with oxirane, ether with 1,2,3-propanetriol or tetrakis[methylene(2,5-di-*tert*-butyl; -4-hydroxyhydrocinnamate)]methane are cancer-causing chemicals. However, ethylene oxide and 1,4-dioxane, which could be present as impurities in the reactants methyl oxirane polymer with oxirane and methyl oxirane polymer with oxirane, ether with 1,2,3-propanetriol, have been shown to cause cancer in test animals. Residual amounts of reactants and byproducts, such as ethylene oxide and 1,4 dioxane, are commonly found as contaminants in chemical products, including food additives.

The petitioner also stated that diphenylmethane diisocyanate (MDI) currently regulated in § 177.1680, would be the isocyanate of choice for reaction with the above listed compounds. Therefore, FDA has reviewed the safety of the polyurethane resins for the presence of MDI, a potential impurity in the polyurethanes resins resulting from the manufacture with this chemical. The agency is concerned that some of the MDI that may migrate to food could react with atmospheric moisture or could hydrolyze during cooking or ingestion and form methylenedianiline (MDA), a carcinogen. Therefore, the agency has evaluated the safety of the potential ingestion of this carcinogenic substance from the use of polyurethane resins.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain carcinogenic chemicals but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis.

An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use of the Additives

FDA estimates that the petitioned use of polyurethane resins, prepared from the designated five reactants and the optional adjuvant, will result in extremely low levels of exposure to polyurethane resins manufactured with these components. The agency has calculated the estimated daily intake of polyurethane additive resins based on considerations such as the migration of polyurethane under the most severe intended use conditions and the probable concentration of polyurethane in the daily diet from food-contact articles that contain this substance. Based upon this information the agency estimates the potential daily intake for the polyurethane resins to be 8.2 micrograms per person per day.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2), and the agency has not required such testing here. However, the agency has reviewed available data from acute toxicity studies in rats and rabbits as well as subchronic rat and dog feeding studies in support of the proposed use of the polyurethane resins. On the basis of this information, and the low level of exposure of the polyurethane resin, the agency concludes that there is an adequate margin of safety for the proposed use of the resins manufactured with these new components.

FDA has also evaluated the safety of these polyurethane resins under the general safety clause, using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemicals 1,4-dioxane and ethylene oxide, which may be present as impurities in two of the reactants, methyl oxirane polymer with oxirane and methyl oxirane polymer with oxirane, ether with 1,2,3-propanetriol. Additionally, the agency has evaluated the possible ingestion of MDA resulting from the hydrolysis of MDI which could be present in food packaged in the polyurethane resins. MDI can react with atmospheric moisture or hydrolyze during cooking or ingestion to MDA. FDA therefore evaluated the safety of MDA under the general safety clause using risk assessment procedures to estimate the upper-bound limit of risk presented by

this carcinogen. Based on this evaluation, the agency concludes that the polyurethane resins are safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that the agency has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities. (See, e.g., 49 FR 13018 at 13019; April 2, 1984). The risk evaluation of the carcinogenic impurities has two aspects:

(1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive, and

(2) Extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. 1,4-Dioxane

Based on the fraction of the daily diet that may be in contact with surfaces containing polyurethane resin and on the level of 1,4-dioxane that may be present in the finished polyurethane resins (Ref. 3), FDA estimated the hypothetical worst-case exposure to 1,4-dioxane from the use of this additive to be 8.2 picograms (pg) per person per day. The agency used data from a carcinogenesis bioassay on 1,4-dioxane conducted by the National Cancer Institute (Ref. 4) to estimate the upper-bound level of lifetime human risk from exposure to this chemical resulting from the proposed use of the polyurethane resins. The results of the bioassay on 1,4-dioxane indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Quantitative Risk Assessment Committee (the Committee) reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The Committee further concluded that the 1,4-dioxane bioassay provided the appropriate basis on which to calculate an estimate of the upper-bound level of lifetime human risk from potential exposure to 1,4-dioxane stemming from the proposed use of polyurethane resins.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the food additive. Based on a worst-case exposure of 8.2 pg per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from potential exposure to 1,4-dioxane from the proposed use of the polyurethane resins is 2.7×10^{-13} or less than 1 in 3.7 trillion (Ref. 5). Because of numerous conservatisms in the exposure estimate, actual lifetime averaged individual exposure to 1.4-dioxane is expected to be substantially less than the estimated daily intake and, therefore, the calculated upper-bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to 1,4-dioxane that might result from the proposed use of the polyurethane resins.

B. Ethylene Oxide

Based on the fraction of the daily diet that may be in contact with surfaces containing polyurethane resin and the level of ethylene oxide that may be present in the finished resins (Ref. 3), FDA estimated the hypothetical worst-case exposure to ethylene oxide from the use of this additive to be 8.2 pg per person per day. The agency used data from a carcinogenesis bioassay on ethylene oxide, conducted by the Institute of Hygiene, University of Mainz, Germany (Ref. 6), to estimate the upper-bound level of lifetime human risk from exposure to this chemical resulting from the proposed use of the polyurethane resins. The results of the bioassay on ethylene oxide demonstrated that this material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinoma in situ of the forestomach and carcinoma in situ of the glandular stomach.

The Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on ethylene oxide. The Committee further concluded that the ethylene oxide bioassay provided the appropriate basis on which to calculate an upper-bound level of lifetime human risk from the potential exposure to ethylene oxide stemming from the proposed use of the polyurethane resins.

Based on a worst-case exposure of 8.2 pg per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from potential exposure to ethylene oxide from the proposed use of the polyurethane resins is 1.5×10^{-11} or less than 1 in 66 billion (Ref. 5). Because of the numerous conservatisms in the exposure estimate, actual lifetime averaged individual exposure to ethylene oxide is expected to be substantially less than the estimated daily intake and, therefore, the calculated upper-bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that might result from the use of the polyurethane resins.

C. Methylenedianiline

Based on the fraction of the diet that may be in contact with surfaces containing the polyurethane resin and on the level of MDI that may be present in the resin and which could possibly react to form MDA, FDA estimated the worst-case exposure to MDA from the use of MDI to manufacture polyurethane resin to be 6.4 nanograms (ng) per person per day. This estimate is based on the assumption that all of the MDI that could migrate to food undergoes hydrolysis to MDA and is ingested (Ref. 7). The agency used data from a National Toxicology Program technical report on a carcinogenesis bioassay on MDA (also referred to as 4,4-diphenylmethanediamine in this bioassay) to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the additive (Ref. 8). The results of the bioassay on MDA indicated that the material was carcinogenic for mice and rats of both sexes under the conditions of the study. The test material caused a significantly increased incidence of follicular cell tumors of the thyroid in male rats, hepatocellular carcinomas in mice, follicular cell adenomas in mice and female rats, pheochromocytomas in male mice, malignant lymphomas in female rats and neoplastic nodules in the liver of male rats. In addition, several rare tumors (bile duct adenoma in male rats, and ovarian granulosa-cell tumors and urinary bladder transitional-cell papillomas in female rats) were observed in this study.

The Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on MDA. The Committee further concluded that the MDA bioassay provided the

appropriate basis on which to calculate an estimate of the upper-bound level of lifetime human risk from potential exposure to MDA stemming from the proposed use of the polyurethane resins.

Based on a worst-case exposure of 6.4 ng per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from potential exposure to MDA from the proposed use of the polyurethane additive is 6.4×10^{-9} or less than 1 in 160 million (Ref. 5). Because of numerous conservatisms in the exposure estimate, actual lifetime averaged individual exposure to MDA is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper-bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to MDA that might result from the proposed use of the polyurethane resins.

D. Need for Specifications

The agency has also considered whether specifications are necessary to control the amounts of 1,4–dioxane, ethylene oxide, and MDA in the polyurethane resins. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which 1,4–dioxane, ethylene oxide, and MDA may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely small levels; and (2) the upper-bound limit of lifetime risk from exposure to these impurities, even under worst-case assumptions, is very low, less than 1 in 3.7 trillion for 1,4–dioxane, less than 1 in 66 billion for ethylene oxide and less than 1 in 160 million for MDA.

III. Conclusion on Safety

FDA has evaluated the available toxicity data in the petition and other relevant material and concludes that the proposed reactants and adjuvant used in the production of polyurethane resins in contact with bulk quantities of dry food is safe and that § 177.1680 should be amended in paragraphs (a) and (b) to provide for their safe use as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA consider and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 16, 1991, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carr, G.M., "Carcinogen Testing Programs" in "Food Safety: Where Are We?," Committee on Agriculture, Nutrition, and Forestry, United States Senate, p. 59, July 1979.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology," presented at the Second International Conference on Safety Evaluation and Regulation of Chemicals, October 24, 1983, Cambridge, MA.

3. Memorandum dated February 22, 1989, from Food and Color Additives Review Section to Indirect Additives Branch, FAP 7B4038—The Dow Chemical Corp.

4. "Bioassay of 1,4–Dioxane for Possible Carcinogenicity," National Cancer Institute, NCI–CG–TR–80, 1978.

5. Memorandum dated October 27, 1989, from the Quantitative Risk Assessment Committee to the Office of Toxicological Sciences Re: Methylene dianiline (MDA), ethylene oxide (EO), and 1,4–dioxane (DO) impurities in FAP 7B4038.

6. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2–Propylene Oxide upon Intragastric Administration to Rats," British Journal of Cancer, 46:924, 1982.

7. Memorandum dated October 19, 1989, from Food and Color Additives Review Section, FAP 7B4038—In vivo hydrolysis of diphenylmethane diisocyanate (MDI).

8. Carcinogenesis bioassay of 4,4'–methylenedianiline dihydrochloride (MDA) (CAS Reg. No. 1355–44–8) in F344/N Rats and B6C3F, Mice.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 177.1680 is amended in paragraph (a)(2) by alphabetically adding the following entries and in the table in paragraph (b) by alphabetically adding a new entry under the headings "List of Substances" and "Limitations" to read as follows:

§ 177.1680 Polyurethane resins.

* * * * *

(a) * * *

(2) List of substances:

* * * * *

1,4–Cyclohexane dimethanol (CAS Reg. No. 105–08–8).

* * * * *

1,6–Hexanediol (CAS Reg. No. 629–11–8).α–Hydro–ω–hydroxypoly(oxy–1,4–butanediyl) (CAS Reg. No. 25190–06–1).

* * * * *

Methyl oxirane polymer with oxirane (CAS Reg. No. 9003–11–6).

Methyl oxirane polymer with oxirane, ether with 1,2,3–propanetriol (CAS Reg. No. 9082–00–2).

* * * * *

(b) * * *

List of substances	Limitations
* * * * *	
Tetrakis [methylene–(2,5–di–*tert*–butyl–4–hydroxyhydrocinnamate)]methane (CAS Reg. No. 6683–19–8).	Stabilizer.
* * * * *	

* * * * *

Dated: April 9, 1991.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 91–8919 Filed 4–15–91; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

Kentucky Regulatory Program; Procedures, Criteria and Schedule for Release of Performance Bond

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of a proposed amendment to the Kentucky regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment consists of a proposed modification to Kentucky Administrative Regulations (KAR) at 405 KAR 10:040, the regulations governing Kentucky's performance bond release. The modification will, except for prime farmlands, exclude completion of productivity standards from the revegetation success standards that must be met to qualify for Phase II bond release.

EFFECTIVE DATE: April 16, 1991.

FOR FURTHER INFORMATION CONTACT: William Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 340 Legion Drive, suite 28, Lexington, Kentucky 40504, Telephone (606) 233–7327.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program

The Secretary of the Interior conditionally approved the Kentucky regulatory program effective May 18, 1982. Information pertinent to the general background and revisions to the permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 917.11, 30 CFR 917.13, 30 CFR 917.15, 30 CFR 917.16 and 30 CFR 917.17.

II. Submission of the Amendment

By letter dated January 9, 1991, (Administrative Record Number KY–1020), Kentucky submitted a program amendment to OSM containing a proposed change to 405 KAR 10:040 section 2(4)(b)1. OSM announced receipt of the proposed amendment in the February 5, 1991, **Federal Register** (56 FR 4590–4591), and in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period ended on March 7, 1991.

III. Director's Findings

Set forth below pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Kentucky program.

405 KAR 10:040 Section 2(4)(b)1

The amendment will, except on prime farmlands, exclude productivity standards from the revegetation success standards which must be met to qualify for Phase II bond release. This change is consistent with OSM's current interpretation of the corresponding Federal regulation at 30 CFR 800.40(c)(2). OSM's policy, other than for prime farmland, is that revegetation need only be successfully established (planted in accordance with the reclamation plan with growth adequate to control erosion) in order to qualify for a Phase II bond release, and need not meet the success standards approved in accordance with 30 CFR 816.116 and 817.116.

Section 519(c) of SMCRA establishes a phased schedule for bond release. Paragraph (c)(2) of this section provides that a portion of the bond may be released:

(a) after revegetation has been established on the regraded mined lands in accordance with the approved reclamation plan. When determining the amount of bond to be released after successful revegetation has been established, the regulatory authority shall retain that amount of bond for the revegetated area which would be sufficient for a third party to cover the cost of reestablishing revegetation and for the period specified for operator responsibility in section 515 of reestablishing revegetation.

This language indicates that Congress intended to allow partial bond release after revegetation has been successfully established, but before the final determination or demonstration of revegetation success is made. Otherwise, there would be little purpose in requiring retention of that amount of bond necessary to reestablish revegetation or in providing for this phase of bond release, which would likely differ little in timing from final bond release.

In other words, in recognition of the progressive nature of vegetative stand development, Congress anticipated the establishment of two differing standards for revegetation success, one for Phase II bond release following successful establishment of the initial planting and one for final bond release upon expiration of the revegetation responsibility period. As revised on July 19, 1983, the Federal rule at 30 CFR 800.40(c) implementing this statutory provision essentially repeats the statutory language.

OSM holds that, except for prime farmlands, attainment of the success standards of 30 CFR 816.116 and 817.116 is a prerequisite only for final bond release. Neither SMCRA nor the federal regulations define successful revegetation in relation to Phase II bond release. Thus, State regulatory authorities are free to establish standards to determine when revegetation is successfully established for purposes of Phase II bond release. Such standards must be consistent with the conventional meanings of the terms "successful" and "established" and the revegetation must be adequate to control erosion and in accordance with approved reclamation plan.

However, as stated above, OSM through policy has defined successful revegetation with respect to Phase II bond release. The Kentucky amendment meets OSM's policy. The regulation specifically states that for Phase II bond release to occur, revegetation must be established in accordance with the approved reclamation plan. Kentucky has also indicated, in its January 9, 1991 submission, that "[o]ther applicable standards such as ground cover will