

gas producing activities compute amortization based on the gross revenue method described in the above rule when substantial production is not subject to pricing regulation?

Interpretive Response: Yes. Under the existing rules for cost amortization adopted in Accounting Series Release No. 258,¹ the use of the gross revenue method of amortization was permitted in those circumstances where, because of the effect of existing pricing regulations, the use of the units of production method would result in an amortization provision that would be inconsistent with the current prices being received. While the effect of regulation on gas prices has lessened, factors other than price regulation (such as changes in typical contract lengths and methods of marketing natural gas) have caused oil and gas prices to be disproportionate to their relative energy content. The staff therefore believes that it may be more appropriate for registrants to compute amortization based on the gross revenue method whenever oil and gas sales prices are disproportionate to their relative energy content to the extent that the use of the units of production method would result in an improper matching of the costs of oil and gas production against the related revenue received. The method should be consistently applied and appropriately disclosed within the financial statements.

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G. Inclusion of Methane Gas in Proved Reserves

Facts: Because of a concern over worldwide oil and gas supplies, Congress, in 1980, provided for tax incentives (credits) for the production of oil and gas from other than conventional sources.² As a consequence, significant amounts of gas have begun to be recovered from seams of coal beds. This gas is referred to as coalbed methane. It is produced using conventional drilling methods, but for various reasons, it may be more costly to produce than oil and gas recovered from customary sources and some reserves may not be economical without the tax credits.

Rule 4-10(a)(1)(i)(A) of Regulation S-X indicates that oil and gas producing activities include the search for crude oil, including condensate and natural gas liquids, or natural gas in their natural states and original locations. Rule 4-10(a)(2)(iii)(D) of Regulation S-X states that estimates of proved reserves

do not include (among other things) natural gas that can be recovered from coal.³ In addition, the definition of proved oil and gas reserves includes a provision that the quantities of natural gas be recovered from existing reservoirs. Under these definitions, "coalbed methane" gas has generally not been included in the disclosures required in Commission filings by Rule 4-10(k) of Regulation S-X. Further, coalbed methane has generally not been counted in proved oil and gas reserves for purposes of the full cost ceiling test in Rule 4-10(i)(4) since that test is based on the same definition of proved oil and gas reserves.

Question: Is it appropriate to consider coalbed methane gas within the definition of proved reserves for purposes of the disclosures relating to oil and gas producing activities and the full cost ceiling test?

Answer: Yes. The prohibition against the inclusion of gas derived from coal was meant to apply to the recovery of hydrocarbons from the processing of coal. The extraction of methane gas from coalbed seams using conventional methods was not contemplated at the time Rule 4-10(a) was developed. The staff believes that, since coalbed methane gas can be recovered from coal in its natural state and original location, it should be included in proved reserves, provided that it complies in all other respects with the definition of proved oil and gas reserves as specified in Rule 4-10(a)(2) including the requirement that methane production be economical at current prices, costs (net of the tax credit) and existing operating conditions.⁴ Methane gas from coalbeds (like any other hydrocarbon obtained from conventional reservoirs) that cannot be produced at a profit under current economic and operating conditions, or for which there is no market or any existing method of delivery to the market, cannot be included in the category of proved reserves.

In instances where methane gas is deemed to be economically producible only as a consequence of existing Federal tax incentives, the staff believes that additional disclosure should be

³ Similar language appears in Statement of Financial Accounting Standards No. (SFAS) 25, *Suspension of Certain Accounting Requirements for Oil and Gas Producing Companies*, and SFAS No. 19, *Financial Accounting and Reporting by Oil and Gas Producing Companies*.

⁴ Proved oil and gas reserves are the estimated quantities of crude oil, natural gas, and natural gas liquids which geological and engineering data demonstrate with reasonable certainty to be recoverable in future years from known reservoirs under existing economic and operating conditions. (Emphasis added.)

provided as to the specific quantities and values of reported proved reserves that are dependent on existing U.S. tax policy together with any other information necessary to inform readers of the risks attendant with any future change to existing Federal tax policy.

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DEPARTMENT OF LABOR

Office of the Assistant Secretary for Veterans' Employment and Training

Employment and Training Administration

20 CFR Chapters V and IX

20 CFR Parts 626, 635, 636, 652, 653, 1001, and 1005

RIN 1293-AA03

Veterans' Employment and Training Services: Addition of Chapter and Redesignation of Regulations

AGENCIES: Office of the Assistant Secretary for Veterans' Employment and Training, Labor; Employment and Training Administration, Labor.

ACTION: Final rule.

SUMMARY: The Department of Labor is amending Title 20, Code of Federal Regulations by adding a new Chapter IX to consolidate regulations of the Office of the Assistant Secretary for Veterans' Employment and Training.

EFFECTIVE DATE: October 26, 1989.

FOR FURTHER INFORMATION CONTACT: Mr. Carlon J. Johnson. Telephone: (202) 523-8611 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department of Labor's Office of the Assistant Secretary for Veterans' Employment and Training (OASVET) was established by the Veterans' Rehabilitation and Education Amendments of 1980, Pub. L. 96-466 (October 17, 1980) and has been given the primary responsibility for administering the programs and activities within the U.S. Department of Labor (Labor) relating to veterans. These include the veterans' employment and training services enacted under the Job Training Partnership Act and the Wagner-Peyser Act, originally administered by the Employment and Training Administration (ETA) and then transferred to OASVET, pursuant to 38 U.S.C. 2002A(a)(4), 2002A(d), 2009 and 29 U.S.C. 1721. With the enactment of the Veterans' Employment, Training and

¹ 43 FR 60415 (December 27, 1978).

² Section 29 of the Federal Tax Code provides for Credit for Producing Fuel from a Nonconventional Source.

Counseling Amendments of 1988, Pub. L. 100-323 (May 20, 1988), the role of OASVET was expanded further. Therefore, it has become necessary to establish a new Chapter in the Code of Federal Regulations to accommodate the number of rules that will be needed to implement OASVET's greater responsibilities. In addition, it is appropriate to consolidate all present and future OASVET rules in one place and to separate the rules of ETA from those of OASVET, in order to better distinguish the roles and functions of the two agencies, as well as for ease of reference.

Publication in Final

This rulemaking only redesignates existing regulations and adds a new chapter to the Code of Federal Regulations. As such, it is a rule of agency organization and procedure for which no general notice of proposed rulemaking is required by law. 5 U.S.C. 553(b)(A).

Also, pursuant to 5 U.S.C. 553(b)(B), the Department of Labor has determined that public comment on this rulemaking is unnecessary, and good cause exists for not publishing a proposed rule, because the redesignation does not change the text of the regulations, which had originally been duly promulgated, with appropriate notice and an opportunity for comment.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for the rule under 5 U.S.C. 553(b), the requirements of the Regulatory Flexibility Act, Pub. L. 96-354, Stat. 1165, 5 U.S.C. 601 *et seq.*, pertaining to regulatory flexibility analysis, do not apply to this rule. 5 U.S.C. 601(2). In any event, the rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

Paperwork Reduction Act

Since the establishment of a new chapter and redesignation of portions of the CFR require no additional collection of information, approval of the Office of Management and Budget is not required, pursuant to the Paperwork Reduction Act. 44 U.S.C. 3501 *et seq.*

Executive Order 12291

The Department has determined that this rule is not classified as a "major rule" under Executive Order 12291 on Federal Regulations, because it is not likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government

agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Accordingly, no regulatory impact analysis is required.

List of Subjects

20 CFR Part 626

Manpower training programs.

20 CFR Parts 635, 1005

Manpower training programs, reporting and recordkeeping requirements, veterans.

20 CFR Parts 652, 1001

Reporting and recordkeeping requirements, veterans.

Final Rule

For the reasons set forth in the preamble, title 20 of the Code of Federal Regulations is amended as follows:

1. A new chapter IX is added to title 20, having a heading reading as follows:

Chapter IX—Office of the Assistant Secretary for Veterans' Employment and Training, Department of Labor

2. A new part 1001 is added to chapter IX, having a heading reading as follows:

PART 1001—SERVICES FOR VETERANS

3. The authority citation is added to part 1001 of chapter IX, reading as follows:

Authority: 29 U.S.C. 49k; 38 U.S.C. Chapters 41 and 42.

4. Subparts A, B, C, D, and E are added to part 1001 of Chapter IX, having headings reading as follows:

Subpart A—Purpose and Definitions

Subpart B—Federal Responsibilities

Subpart C—Standards of Performance Governing State Agency Services to Veterans and Eligible Persons

Subpart D—State Employment Service Agency Compliance

Subpart E—Standards of Performance Governing the Disabled Veterans Outreach Program (DVOP)

§§ 652.100 and 652.101 [Redesignated as §§ 1001.100 and 1001.101]

5. Sections 652.100 and 652.101 of part 652, subpart B, of chapter V are redesignated as §§ 1001.100 and 1001.101, respectively, of part 1001, subpart A, of chapter IX.

§ 652.110 [Redesignated as § 1001.110]

6. Section 652.110 of part 652, subpart B, of chapter V is redesignated as § 1001.110 of part 1001, subpart B, of chapter IX.

§§ 652.120 through 652.125 [Redesignated as §§ 1001.120 through 1001.125]

7. Sections 652.120 through 652.125 of part 652, subpart B, of chapter V are redesignated as §§ 1001.120 through 1001.125, respectively, of part 1001, subpart C, of chapter IX.

§§ 652.130 and 652.131 [Redesignated as §§ 1001.130 and 1001.131]

8. Sections 652.130 and 652.131 of part 652, subpart B, of chapter V are redesignated as §§ 1001.130 and 1001.131, respectively, of part 1001, subpart D, of chapter IX.

§§ 652.140 through 652.142 [Redesignated as §§ 1001.140 through 1001.142]

9. Sections 652.140 through 652.142 of part 652, subpart B, of chapter V are redesignated as §§ 1001.140 through 1001.142, respectively, of part 1001, subpart E, of chapter IX.

§ 1001.100 [Amended]

10. Section 1001.100 of part 1001 of chapter IX, as redesignated, is amended by removing from paragraph (d) the phrase "in this subpart at §§ 652.140-652.142" and adding in lieu thereof the phrase "in this part at §§ 1001.140-1001.142".

§ 1001.101 [Amended]

11. Section 1001.101 of part 1001 of chapter IX, as redesignated, is amended by removing from the definition of "Assistant Secretary for Veterans' Employment and Training (ASVET)" the citation "§ 652.110" and adding in lieu thereof the citation "§ 1001.110 of this part"; and by removing from the definition "United States Employment Service (USES)" the term "of 1933".

§ 1001.123 [Amended]

12. Section 1001.123 of part 1001 of chapter IX, as redesignated, is amended by removing from paragraph (a)(2) the citation "§ 652.123(a)(1)" and adding in lieu thereof the citation "paragraph (a)(1) of this section".

13. Section 1001.130 of part 1001 of chapter IX, as redesignated, is amended as follows:

a. Paragraph (a) of § 1001.130 is revised to read as follows:

§ 1001.130 **Determination of compliance.**

(a) The ASVET shall have authority for applying the requirements and remedial actions necessary to implement 20 CFR part 658, subpart H.

In the event of such application, references in 20 CFR part 658, subpart H, to "ETA" shall read instead "OASVET"; references to "Regional Administrator" shall read instead "RDVETS"; and references to "JS regulations" shall include this part.

§ 1001.130 [Amended]

b. Paragraph (b) of § 1001.130 is amended by removing the citation "§§ 652.120-125" and adding in lieu thereof the citation "§§ 1001.120-1001.125 of this part"; by removing the citation "§ 652.120(a)" and adding in lieu thereof the citation "§ 1001.120(a) of this part"; and by removing the citation "§ 652.131 of this subpart" and adding in lieu thereof the citation "§ 1001.131 of this part".

c. Paragraph (d) of § 1001.130 is amended by removing the citation "§ 652.120-125" and adding in lieu thereof the citation "§ 1001.120-1001.125 of this part"; and by removing wherever it appears the phrase "pursuant to subpart H of part 658 of this chapter" and adding in lieu thereof the phrase "pursuant to subpart H of 20 CFR part 658".

§ 1001.131 [Amended]

14. Section 1001.131 of part 1001 of chapter IX, as redesignated, is amended by removing the word "subpart" and adding in lieu thereof the word "part".

§ 1001.140 [Amended]

15. Section 1001.140 is amended by removing from paragraph (c) the citation "§ 652.123 of this subpart" and adding in lieu thereof the citation "§ 1001.123 of this part".

16. The authority citation for part 652 is revised to read as follows:

Authority: 29 U.S.C. 49k; 38 U.S.C. Chapters 41 and 42.

17. A new § 652.100 is added to subpart B of part 652 of chapter V to read as follows:

Subpart B—Services for Veterans

§ 652.100 Services for veterans.

Services for veterans are administered by the Office of the Assistant Secretary for Veterans' Employment and Training (OASVET). OASVET's general regulations are located in chapter IX of this title.

18. Part 635 of chapter V is redesignated as part 1005 of Chapter IX.

19. The authority citation for part 1005, as redesignated, is revised to read as follows:

Authority: 29 U.S.C. 1579(a).

§ 1005. [Amended]

20. Section 1005.1 of part 1005 of chapter IX, as redesignated, is amended by removing the word "Act" and by adding in lieu thereof the phrase "Job Training Partnership Act (Act), Pub. L. 97-300, as amended (29 U.S.C. 1721)".

§ 1005.2 [Amended]

21. Section 1005.2(a) of part 1005 of chapter IX, as redesignated, is amended by adding after the phrase "administered by the Secretary" the words "of Labor (Secretary)".

§ 1005.12 [Amended]

22. Section 1005.12 of part 1005 of chapter IX, as redesignated, is amended by removing from paragraph (b) the phrase "The Department will not favorably consider" and adding in lieu thereof the phrase "The Department of Labor (Department) will not favorably consider"; and by removing from paragraph (c) the citation "§ 635.11(c)" and adding in lieu thereof the citation "§ 1005.11(c) of this part".

§ 1005.13 [Amended]

23. Section 1005.13 of part 1005 of chapter IX, as redesignated, is amended by removing from the introductory language in paragraph (a) the citation "§ 635.11(c)" and adding in lieu thereof the citation "§ 1005.11(c)"; by removing from paragraph (c) the citation "§ 635.11(b)" and adding in lieu thereof the citation "§ 1005.11(b) of this part"; and by removing from paragraph (c) the word "Application" and adding in lieu thereof the word "Applications".

§ 1005.14 [Amended]

24. Section 1005.14 of part 1005 of chapter IX, as redesignated, is amended by removing the citation "§§ 635.12 and 635.13" and adding in lieu thereof the citation "§§ 1005.12 and 1005.13 of this part".

§ 1005.15 [Amended]

25. Section 1005.15 of part 1005 of chapter IX, as redesignated, is amended by removing from paragraph (c) the citation "§ 629.57 of this chapter" and adding in lieu thereof the citation "20 CFR 629.57"; and by removing from paragraph (c) the citation "§ 629.56 of this chapter" and adding in lieu thereof the citation "20 CFR 629.56".

26. Section 1005.21 of part 1005 of chapter IX, as redesignated, is revised to read as follows:

§ 1005.21 General.

(a) The provisions of 20 CFR part 636, relating to complaints, investigations, and hearings for programs under Title IV of the Act, are applicable to programs under this part.

(b) The requirements of 29 CFR parts 96, 97, and 98, implementing the Single Audit Act, uniform administrative requirements for grants and cooperative agreements, and governmentwide debarment and suspension (nonprocurement) apply to grants and agreements under this part.

§ 1005.25 [Amended]

27. Section 1005.25 of part 1005 of chapter IX, as redesignated, is amended by removing from paragraph (b) the citation "§ 629.42 of this chapter" and adding in lieu thereof the citation "20 CFR 629.42"; by removing from paragraph (c) the citation "§ 629.42 of this chapter" and adding in lieu thereof the citation "20 CFR 629.42"; and by removing from paragraph (d) the citation "§ 629.44 of this chapter" in the two places it occurs and adding in lieu thereof the citation "20 CFR 629.44".

27a. The authority citation for part 626 continues to read as follows:

Authority: 29 U.S.C. 1579(a); sec. 6305(f), Pub. L. 100-418, 102 Stat. 1107.

28. Section 626.2 of part 626 of chapter V is amended by revising paragraph (a) to read as follows:

§ 626.2 Format of these regulations.

(a) Regulations promulgated by the Department of Labor to implement the provisions of the Act are set forth in parts 626 through 638 of title 20, chapter V, of the Code of Federal Regulations, with the exceptions of the Job Corps regulations, which are set forth at part 684 of title 20, chapter V, and the veterans' employment program regulations of the Office of the Assistant Secretary for Veterans' Employment and Training, which are set forth at part 1005 of title 20, chapter IX.

§ 626.3 [Amended]

29. Section 626.3 of part 626 of chapter V is amended as follows:

a. By removing from the consolidated table of contents the table of contents for part 635 of chapter V; and

b. By revising the introductory text to the section and by adding at the end of the consolidated table of contents a table of contents for part 1005 of chapter IX, to read as follows:

§ 626.3 Table of contents for the regulations under the Job Training Partnership Act.

The table of contents for the regulations under the Job Training Partnership Act, parts 626-638, 684, and 1005, is as follows:

PART 1005—Veterans' Employment Programs Under Title IV, Part C of the Job Training Partnership Act

Subpart A—General Provisions

Sec.

- 1005.1 Scope and purpose.
- 1005.2 Program administration.
- 1005.3 Participant eligibility.

Subpart B—Program Funding

- 1005.11 Availability of funds.
- 1005.12 Eligibility for funds.
- 1005.13 Application for funding.
- 1005.14 Review of application for funding.
- 1005.15 Approval of funding requests.

Subpart C—Program Design and Management

- 1005.21 General.
- 1005.22 Allowable activities.
- 1005.23 Program management and reporting requirements.
- 1005.24 Recordkeeping and reporting requirements.
- 1005.25 Monitoring and oversight.
- 1005.26 Grievance procedures.

29a. The authority citation for part 653 continues to read as follows:

Authority: 38 U.S.C. chapters 41 and 42; Wagner-Peyser Act, as amended, 29 U.S.C. 49 et seq.; sec. 104 of the Emergency Jobs and Unemployment Assistance Act of 1974 Pub. L. 93-567, 88 Stat. 1845, unless otherwise noted.

Subpart C—[Removed]

30. In part 653 of chapter V, subpart C is removed.

Signed at Washington, DC, this 18th day of September, 1989.

Donald E. Shasteen,

Assistant Secretary for Veterans' Employment and Training.

Roberts T. Jones,

Assistant Secretary for Employment and Training.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 82F-0229]

Indirect Food Additives, Adjuvants, Production Aids, and Sanitizers.

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of styrenated diphenylamine as an antioxidant in adhesives and polymers for food-contact

use. This action responds to a petition filed by Goodyear Tire & Rubber Co.

DATES: Effective September 26, 1989; written objections and requests for a hearing by October 26, 1989.

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

FOR FURTHER INFORMATION CONTACT: Richard H. White, 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 August 13, 1982 (47 FR 35343), FDA announced that a petition (FAP 2B3637) had been filed by Goodyear Tire & Rubber Co., Akron, OH 44316, proposing that § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) be amended to provide for the safe use of styrenated diphenylamine in § 175.105 Adhesives (21 CFR 175.105) and in § 177.2600 Rubber articles intended for repeated use (21 CFR 177.2600).

FDA, in its evaluation of the safety of styrenated diphenylamine, has reviewed the safety of the additive, the starting materials used to manufacture the additive, the byproducts of the reactants, and the manufacturing impurities that may be present in the additive. Although the additive itself has not been found to cause cancer, it has been found to contain minute amounts of aniline and 4-aminobiphenyl (4/ABP) as impurities carried through the production process and minute amounts of quinoline as a byproduct impurity of its production. These chemicals have been shown to cause cancer in test animals. Residual amounts of reactants, byproducts, and impurities, such as aniline, 4-ABP, and quinoline, are commonly found as contaminants in chemical products, including food additives.

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 of 1958 (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 a 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 a carcinogenic chemical 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 impurity 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 U.S. 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

The agency estimated the daily intake of styrenated diphenylamine in

adhesives and rubber articles intended for repeated food-contact use based on several factors, including an analysis of several product applications and the probable concentration of the additive in food-contact articles and rubber articles for repeated use. The agency found that these uses will result in an extremely low level of exposure to this additive.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in very low exposure levels (Refs. 1 and 2), and the agency has not required such testing in this case. However, the agency has reviewed available data from an acute toxicity study on styrenated diphenylamine in the rat. No adverse effects were reported in this study. Because the additive itself has not been shown to cause cancer, the anticancer clause does not apply to it. However, FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemicals, aniline, 4-ABP, and quinoline that may be present as impurities in this additive. Based on this evaluation, FDA has concluded that the additive is 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, 13019; April 2, 1984). The risk evaluation of the carcinogenic impurities aniline, 4-ABP, and quinoline has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed uses of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. Aniline

Based on the fraction of the daily diet that may be in contact with surfaces containing styrenated diphenylamine, and on the level of aniline that may be present in the additive, FDA estimated that the hypothetical worst-case exposure to aniline from the use of the additive in adhesives and repeated use rubber articles would not exceed 0.3 picogram per person per day (Ref. 3). The agency used data from a carcinogenesis bioassay on aniline conducted for the Chemical Industry Institute of Toxicology to estimate the upper-bound limit of lifetime human risk

from exposure to aniline stemming from the proposed use of the additive (Ref. 4). The results of the bioassay on aniline demonstrated that the material was carcinogenic for rats under the conditions of the study, inducing fibrosarcoma, stromal sarcoma, capsular sarcoma, hemangiosarcoma, and osteogenic sarcoma of the spleen.

FDA reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on aniline (Ref. 5). The agency further concluded that an estimate of the upper-bound level of human risk from potential exposure to aniline stemming from the proposed use of the antioxidant could be calculated from the bioassay. The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiments 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 0.3 picogram per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to aniline from the use of the styrenated diphenylamine is 3×10^{-15} or 1 in 300 trillion (Ref. 5). Because of the numerous conservatisms in the exposure estimate, lifetime-averaged individual exposure to aniline is expected to be substantially less than the estimated daily intake. 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 aniline that results from the proposed use of the additive.

B. 4-Aminobiphenyl (4-ABP)

Based on the fraction of the daily diet that may be in contact with surfaces containing styrenated diphenylamine, as well as the level of 4-ABP that may be present in the additive (Ref. 3), FDA estimated that the hypothetical worst-case exposure to 4-ABP would not exceed 30 picograms per person per day (Ref. 3). The agency used data in a carcinogenesis bioassay on 4-ABP contained in a dog study reported by both Block, et al., and Rippe, et al., to

estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of styrenated diphenylamine. The results of the bioassay on 4-ABP demonstrated that this material was carcinogenic for female beagle dogs under the conditions of the study, inducing papilloma of the bladder (Refs. 7 and 8).

FDA reviewed the bioassay and other relevant data available in the literature and concluded that this information on 4-ABP supported the finding of carcinogenicity. The agency further concluded that an estimate of the upper-bound level of lifetime human cancer risk from potential exposure to 4-ABP stemming from the proposed use of the antioxidant could be calculated from the bioassay (Ref. 5).

Based on a worst-case exposure of 30 picograms per person per day (Ref. 3), FDA estimates, using the linear proportional model, that the upper-bound level of individual lifetime risk from potential exposure to 4-ABP from the use of styrenated diphenylamine is 1.0×10^{-10} or less than 1 in 10 billion (Ref. 5). Because of numerous conservatisms in the exposure estimate, lifetime-averaged individual exposure to 4-ABP 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 4-ABP that might result from the proposed use of the styrenated diphenylamine antioxidant.

C. Quinoline

Based on the fraction of the daily diet that may be in contact with surfaces containing styrenated diphenylamine, as well as the level of quinoline that may be present in the additive, FDA estimated that the hypothetical worst-case exposure to quinoline would not exceed 0.6 picogram per person per day (Ref. 3).

The agency used data in a carcinogenesis bioassay on quinoline contained in the reports by Hirao, K., et al., and Shinohara, Y., et al. (Refs. 8 and 9), to estimate the upper-bound level of lifetime human risk from this chemical stemming from the proposed use of the styrenated diphenylamine. The results of the bioassay on quinoline demonstrated that the material was carcinogenic for female rats and mice under the conditions of the study, inducing vascular tumors of the liver.

FDA reviewed this bioassay and other relevant data available in the literature and concluded that the findings of

carcinogenicity were supported by this information on quinoline. The agency further concluded that an estimate of the upper-bound limit of human risk from potential exposure to quinoline stemming from the proposed use of the antioxidant could be calculated from the bioassay (Ref. 10).

Based on a worst-case exposure of 0.6 picogram per person per day, FDA estimates that the upper-bound level of individual lifetime risk from potential exposure to quinoline from the use of the styrenated diphenylamine is 6×10^{-12} or 1 in 166 billion (Ref. 10). Because of the numerous conservatism in the exposure estimate, lifetime-averaged individual exposure to quinoline 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 quinoline that might result from the proposed use of this styrenated diphenylamine antioxidant.

III. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of the aniline, 4-ABP, and quinoline impurities in the styrenated diphenylamine antioxidant. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which aniline, 4-ABP, and quinoline are present in 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 level of lifetime risk from exposure, even under worst-case assumptions, is very low, 1 in 300 trillion for aniline, less than 1 in 10 billion for 4-ABP, and 1 in 166 billion for quinoline.

IV. Conclusion of Safety

FDA has evaluated the available toxicity data in the petition and other relevant material and concludes that the proposed use of the additive in adhesives and rubber articles for repeated use is safe, and that § 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered 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.

V. 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.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before October 26, 1989, 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.

VII. References

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

1. Carr, G. M., "Carcinogenicity Testing Programs" in "Food Safety: Where Are We?" Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, p. 59, July 1979.
2. Kokoski, C. J., "Regulatory Food Additive Toxicology" in "Chemical Safety Regulation and Compliance," Eds., F. Homburger and J. K. Marquis, S. Karger, New York, pp. 24-33, 1985.

3. Memorandum dated August 15, 1988, from Food and Color Additive Review Section to Indirect Additives Branch, "Submission of IAB Exposure Request of 8/1/88, 10/17/88, and 7/11/88," (Exposure request for aniline, 4-aminobiphenyl, and quinoline).

4. Hazleton Laboratories America, Inc., "104-Week Chronic Toxicity Study in Rats, Aniline Hydrochloride Final Report," Vols. I and II.

5. Memorandum of November 21, 1989, Report of the Quantitative Risk Assessment Committee, "Assessment of Carcinogenic Risks from the Impurities, Aniline and 4-Aminobiphenyl."

6. Block, N.L., et al., "The Initiation, Process and Diagnosis of Dog Bladder Cancer Induced by 4-Aminobiphenyl," *Investigative Urology*, 16:50-54, 1978.

7. Rippe, D.F., et al., "Urinary Bladder Carcinogenesis in Dog: Preliminary Studies on Cellular Immunity," *Transplantation Proceedings*, 7:495-501, 1975.

8. Hirao, K., et al., "Carcinogenic Activity of Quinoline on Rat Liver," *Cancer Research*, 36:329-335, 1976.

9. Shinohara, Y., et al., "Effects of Various Factors on the Induction of Liver Tumors in Animals by Quinoline," *Gann*, 68:785-796, 1977.

10. Report of the Quantitative Risk Assessment Committee, "Estimation of Upper-Bound Risks for Quinoline from Proposed Uses in FAP 2B3637" (February 24, 1989).

List of Subjects in 21 CFR Part 178

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 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 178.2010 is amended by alphabetically adding a new entry to the table in paragraph (b) to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

(b)	Substances	Limitations
•	Styrenated diphenylamine (CAS Reg. No. 68442-68-2)	For use only in adhesives complying with § 175.105 of this chapter and in rubber articles intended for repeated use complying with § 177.2600 of this chapter

Dated: September 19, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 89-22602 Filed 9-25-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

28 CFR Part 32

Public Safety Officers' Death Benefits

AGENCY: Bureau of Justice Assistance,
Office of Justice Programs, Justice.

ACTION: Final rule.

SUMMARY: The regulations covering public safety officers' death benefits and the appendix to those regulations are being amended to comply with statutory amendments to the Public Safety Officers' Benefits (PSOB) Act. Changes to the regulation include an increase in the benefit from \$50,000 to \$100,000 and the abolishment of the parental dependency requirement. The level of payment shall also be adjusted annually to reflect the annual percentage change in the Consumer Price Index for All Urban Consumers. And finally, the Director of the Bureau of Justice Assistance is authorized and directed to use up to \$150,000 to establish national programs to assist the families of public safety officers who have died in the line of duty.

EFFECTIVE DATE: September 26, 1989.

FOR FURTHER INFORMATION CONTACT:
Yvette D. Mouton (Attorney Advisor),
202-724-6235.

SUPPLEMENTARY INFORMATION: The purpose of the amendment is to increase the benefits amount of the Public Safety Officers' Benefits Act from \$50,000 to \$100,000, retroactive on June 1, 1988. The requirement for parental dependency has also been abolished. In addition, the payment shall also be adjusted on a yearly basis beginning on October 1, 1988, and on each October 1, thereafter, to reflect the annual percentage change in the Consumer Price Index for All Urban Consumers. And lastly, the Director of the Bureau of Justice Assistance is authorized and directed to use up to \$150,000 to establish national programs to assist the families of public safety officers who have died in the line of duty. This regulation is not a "major rule" under the requirements of Executive Order 12291. A Regulatory Analysis is not required by the Regulatory Flexibility Act, 5 U.S.C. 601-612. The provisions of the Paperwork Reduction Act, 44 U.S.C. 3504(h), do not

apply. An environmental impact statement is not required by the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

List of Subjects in 28 CFR Part 32

Administrative practice and procedure, Claims, Emergency medical services, Law enforcement officers.

For the reasons set out in the preamble, title 28, part 32 of the Code of Federal Regulations are amended as follows.

PART 32—PUBLIC SAFETY OFFICERS' DEATH BENEFITS

1. The authority for 28 CFR part 32 is revised to read as follows:

Authority: Secs. 801(a) and 1204(a) of the Omnibus Crime Control and Safe Streets Act of 1968, 42 U.S.C. 3711, *et seq.*, as amended (Pub. L. 90-351, as amended by Pub. L. 93-83, Pub. L. 93-415, Pub. L. 94-430, Pub. L. 94-503, Pub. L. 95-115, Pub. L. 96-157, Pub. L. 98-473, Pub. L. 99-570, Pub. L. 99-591, and Pub. L. 100-690).

2. Section 32.1 is revised to read as follows:

§ 32.1 Purpose.

The purpose of this regulation is to implement the Public Safety Officers' Benefits Act of 1976 which authorizes the Office of Justice Programs, Bureau of Justice Assistance, to pay a benefit of \$100,000, adjusted in accordance with § 32.3(b), to specified survivors of public safety officers and rescue squad and ambulance crew members found to have died as the direct and proximate result of a personal injury sustained in the line of duty. The Act also authorizes funds to establish national programs to assist the families of public safety officers who have died in the line of duty. The Act is part I of title I of the Omnibus Crime Control and Safe Streets Act of 1968, 42 U.S.C. 3711, *et seq.*, as amended by Pub. L. 93-83, Pub. L. 93-415, Pub. L. 94-430, Pub. L. 94-503, Pub. L. 95-115, Pub. L. 96-157, Pub. L. 98-473, Pub. L. 99-570, Pub. L. 99-591, and Pub. L. 100-690.

3. Section 32.3 is revised to read as follows:

§ 32.3 Coverage.

(a) In any case in which the Bureau determines under regulations issued pursuant to this part, that a public safety officer, as defined in § 32.2(h), has died as the direct and proximate result of a personal injury sustained in the line of duty, the Bureau shall pay a benefit of \$100,000, adjusted in accordance with § 32.3(b), in the order specified in § 32.10, subject to the conditions set forth in § 32.6.

(b) On October 1 of each fiscal year after October 15, 1988, the Bureau shall adjust the level of the benefit payable immediately before such October 1 under paragraph (a) of this section, to reflect the annual percentage change in the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics, occurring in the 1-year period ending on June 1 immediately preceding such October 1.

(c) The amount payable under paragraph (a) of this section with respect to the death of a public safety officer shall be the amount payable under paragraph (a) of this section as of the date of death of such officer.

4. Section 32.6(b) is revised to read as follows:

§ 32.6 [Amended]

(b) The Act applies to state and local public safety officers killed in the line of duty on or after September 29, 1976; Federal public safety officers killed in the line of duty on or after October 12, 1984; and rescue squad or public emergency employees killed in the line of duty on or after October 15, 1986.

5. Section 32.10 is revised to read as follows:

§ 32.10 Order of priority.

(a) When the Bureau has determined that a benefit may be paid according to the provisions of subpart B of this part and § 32.11 of subpart C of this part, a benefit of \$100,000, adjusted in accordance with § 32.3(b), shall be paid in the following order of precedence:

(1) If there is no surviving child of such officer, to the surviving spouse of such officer;

(2) If there are a surviving child or children and a surviving spouse, one-half to the surviving child or children of such officer in equal shares, and one-half to the surviving spouse;

(3) If there is no surviving spouse, to the surviving child or children of such officer, in equal shares; or

(4) If none of the above, to the surviving parents, in equal shares.

(b) If no one qualifies as provided in paragraph (a) of this section, no benefit shall be paid.

6. Section 32.15 is revised to read as follows:

§ 32.15 Determination of dependency.

(a) To be eligible for a death benefit under the Act, a stepchild not living with the deceased officer at the time of the officer's death shall demonstrate that he