

**1. Electrodyne Research Corp.**

[Docket No. QF85-714-000]

October 1, 1985.

On September 19, 1985, Electrodyne Research Corp., (Applicant) 1617 Sweetbriar Road, Gladwyne, Pennsylvania 19035, submitted for filing an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The topping cycle cogeneration facility will be located within the Schuylkill Station presently owned by the Philadelphia Electric Company. Schuylkill Station is located at the intersection of Schuylkill Avenue and Christian Streets in Philadelphia, Pennsylvania. The facility will consist of a boiler, a back pressure turbine-generator set and a condensing turbine-generator set. Steam produced in the boiler is sold in the District steam system. The primary energy source for the facility will be dried processed anthracite culms. The electric power production capacity of the facility will be 62 megawatts. Construction of the facility will commence in the year 1986.

**2. The Energy Systems Company, Inc.**

[Docket No. QF85-719-000]

October 1, 1985.

On September 20, 1985, The Energy Systems Company, Inc. (Applicant) 1810 Craig Road, Suite 201, St. Louis, Missouri 63146, submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The small power production facility will be located in Porter Township, adjacent to the Village of Sheridan in Schuylkill County, Pennsylvania. The facility will consist of a circulating fluidized bed boiler and a condensing steam turbine-generator set. The Primary energy source for the facility will be waste in the form of anthracite culm. The net electric power production capacity of the facility will be 40 megawatts.

**3. Sundial Investment, Inc.**

[Docket No. QF85-723-000]

October 4, 1985.

On September 23, 1985, Sundial Investment Inc., (Applicant), of 807 Ladore Drive, Salt Lake City, Utah 84107 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant

to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The 25 kW hydroelectric project will be located at the Applicant's address. The facility will consist of 4 inch water line 600 yards long to a hydro-generator.

A separate application is required for a hydroelectric project license, preliminary permit or exemption from licensing. Comments on such applications are requested by separate public notice. Qualifying status serves only to establish eligibility for benefits provided by PURPA, as implemented by the Commission's regulations, 18 CFR Part 292. It does not relieve a facility of any other requirements of local, State or Federal law, including those regarding siting, construction, operation, licensing and pollution abatement.

**4. The Townsend Co.**

[Docket No. QF85-724-000]

October 4, 1985.

On September 23, 1985, The Townsend Co., (Applicant) of RFD No. 2, Friendship, Wisconsin 53934 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The small power production facility will be located at the Applicant's address at Friendship, Wisconsin. The facility will burn wood waste to produce 1,340 kW of electricity.

**5. Twin Falls Canal Co.**

[Docket No. QF85-897-000]

October 4, 1985.

On September 12, 1985, Twin Falls Canal Company of P.O. Box 326, Twin Falls, Idaho 83301 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The proposed small power production hydroelectric facility will be located in Twin Falls County, Idaho and will consist of an intake structure, penstock, and power house. The maximum electric power production capacity will be 2,350 kW.

A separate application is required for a hydroelectric project license, preliminary permit or exemption from licensing. Comments on such applications are requested by separate public notice. Qualifying status serves only to establish eligibility for benefits provided by PURPA, as implemented by

the Commission's regulations, 18 CFR Part 292. It does not relieve a facility of any other requirements of local, State or Federal law, including those regarding siting, construction, operation, licensing and pollution abatement.

**Standard Paragraphs**

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

*Secretary.*

[FR Doc. 85-24290 Filed 10-9-85; 8:45 am]

BILLING CODE 6717-01-M

**Oil Pipeline Tentative Valuation**

October 9, 1985.

The Federal Energy Regulatory Commission by order issued February 10, 1978, established an Oil Pipeline Board and delegated to the Board its functions with respect to the issuance of valuation reports pursuant to section 19a of the Interstate Commerce Act.

Notice is hereby given that a tentative valuation is under consideration for the common carrier by pipeline listed below:

1981 Annual Report

Valuation Docket No. PV-1452-000,  
Chase Transportation Company; P.O.  
Box 2256, Wichita, Kansas 67201.

On or before November 8, 1985, persons other than those specifically designated in section 19a(h) of the Interstate Commerce Act having an interest in this valuation may file, pursuant to rule 214 of the Federal Energy Regulatory Commission's "Rules of Practice and Procedure" (18 CFR 385.214), an original and three copies of a petition for leave to intervene in this proceeding.

If the petition for leave to intervene is granted the party may thus come within the category of "additional parties as the FERC may prescribe" under section

19a(h) of the Act, thereby enabling it to file a protest. The petition to intervene must be served on the individual company at its address shown above and an appropriate certificate of service must be attached to the petition. Persons specifically designated in section 19a(h) of the Act need not file a petition; they are entitled to file a protest as a matter of right under the statute.

Francis J. Connor,

Administrative Officer, Oil Pipeline Board.

[FR Doc. 85-24268 Filed 10-9-85; 8:45 am]

BILLING CODE 6717-01-M

## ENVIRONMENTAL PROTECTION AGENCY

[OPTS-91002; TSH-FRL 2865-9]

### 1,3-Butadiene; Decision To Report to the Occupational Safety and Health Administration

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has reasonable basis to conclude that the manufacture of 1,3-butadiene and its processing into polymers present an unreasonable risk of injury to the health of exposed workers. EPA has further determined that this risk may be prevented or reduced to a sufficient extent if action is taken by the Occupational Safety and Health Administration (OSHA) under the Occupational Safety and Health Act (OSHA Act). EPA is submitting to OSHA a report under section 9(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2608(a), that describes the risks of 1,3-butadiene and requests that OSHA respond to EPA within 180 days of the publication of this notice in the Federal Register.

**FOR FURTHER INFORMATION CONTACT:**

Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-543, 401 M Street SW., Washington, D.C. 20460. Toll-free: (800-424-9065). In Washington, D.C.: (554-1404). Outside U.S.A.: (Operator 202-554-1404).

**SUPPLEMENTARY INFORMATION:**

#### I. Introduction

1,3-Butadiene is an industrial chemical produced at a rate of about 3 billion pounds per year in the U.S. and is predominantly used as a monomer in the production of various types of synthetic rubbers, plastics, and resins. 1,3-Butadiene is a gas at ambient temperatures, and a significant route for human exposure is via inhalation of this

chemical in the workplace. Worker exposure may occur during manufacture of the monomer, during processing into polymers, and during fabrication of various products (e.g., tires) from the polymers. Although the total number of workers in the U.S. potentially exposed to 1,3-butadiene may be as high as 65,000, this notice concerns the 5,300 to 8,200 workers exposed to this chemical in 14 plants that produce the monomer and in 40 plants that process the monomer into polymers.

The EPA determined, under section 4(f) of TSCA, 15 U.S.C. 2603(f), that there may be a reasonable basis to conclude that 1,3-butadiene presents a significant risk of serious harm to humans from cancer, as published in the Federal Register of January 5, 1984 (49 FR 845). This is known as the 4(f) threshold determination. Under section 4(f), EPA has 180 days from receipt of the information that led to the threshold determination to "initiate appropriate action" to prevent or reduce the risk from the chemical of concern or to announce that the risk is not unreasonable.

The section 4(f) threshold determination notice for 1,3-butadiene was primarily based on two animal studies which demonstrated that the chemical is carcinogenic via inhalation in both sexes of rats and mice at two dose levels (Refs. 4 and 9). Based on these studies, as well as other supportive evidence, 1,3-butadiene was considered a potential human carcinogen. The Agency's section 4(f) threshold determination was also based on available information indicating that in facilities where 1,3-butadiene is polymerized into rubber and plastics, some workers in certain job categories may be exposed to levels of 1,3-butadiene roughly equivalent to those that produced tumors in the experimental animals, and many other workers are exposed to lower yet significant levels. OSHA's current workplace standard of 1,000 parts per million (ppm) for 1,3-butadiene, which was established in the 1960s, is based solely on acute toxicity rather than carcinogenic potential.

The Agency is currently compiling information on occupational exposures to 1,3-butadiene other than those in monomer and polymer plants—primarily in rubber tire manufacturing facilities, and also on non-occupational exposures, especially on the potential contamination of the ambient air. EPA will shortly announce the results of its preliminary assessment of the need to regulate 1,3-butadiene under the Clean Air Act to protect the public from ambient-air exposures. Also, the Agency

is assessing waste streams from 1,3-butadiene production facilities to determine whether they should be listed as hazardous waste under the Resource Conservation and Recovery Act. If risks other than those related to contamination of the ambient air or to industrial waste streams are identified, the Agency would take action under the appropriate statute(s) to reduce such risks.

Within the 180-day statutory time frame, designated by section 4(f) of TSCA, EPA "initiate[d] appropriate action." The initiation consisted of the issuance of an Advance Notice of Proposed Rulemaking (ANPR) published in the Federal Register of May 15, 1984 (49 FR 20524). The ANPR announced the initiation of regulatory action by the EPA to determine and implement the most effective means of controlling exposures to 1,3-butadiene. An announced intention of the ANPR was to determine whether any of EPA's legislative authorities or the OSHA Act, administered by OSHA, provided the most appropriate basis for regulation. The ANPR invited public comments and relevant data in five general areas: (1) Health effects; (2) manufacturing, processing, use, and disposal; (3) human exposures; (4) appropriate controls and their cost; and (5) substitutes.

Seven organizations responded to the ANPR: four trade associations, two individual companies, and one public interest group (Refs. 1 through 3 and 5 through 8). While the seven sets of comments dealt in some detail with numerous issues related to the aforementioned five general areas, the essence of the comments can be characterized by the commenters' two diametrically opposite conclusions. The industry-affiliated commenters stated that 1,3-butadiene poses no unreasonable health risks and there is no justification for regulatory action at this time, and that in any case it is not EPA but OSHA which has jurisdiction over workplace-related exposures to toxic chemicals. The Natural Resources Defense Council (NRDC), on the other hand, urged EPA to use its authority under section 6 of TSCA to reduce occupational exposures to 1,3-butadiene by instituting manufacturing and processing controls, instead of shifting the regulatory responsibility to OSHA under section 9(a). NRDC also urged EPA to address all human exposures to 1,3-butadiene, including environmental releases to the air, soil, and ground water.

Following the issuance of the ANPR, the Agency continued its regulatory investigation by conducting further

assessments of the health effects, occupational exposures, health risks, risk control methods and costs, and the availability of substitutes for 1,3-butadiene. As a result of the information submitted in response to the ANPR and other information developed by EPA, the Agency has determined that a revised workplace standard may reduce the risks to a sufficient extent, and appears technically and economically feasible. The Agency's determination with respect to workplace exposure addresses only workplace risks and does not consider risks from other exposure sources.

Based on the entire record developed during EPA's regulatory investigation, the Agency has reasonable basis to conclude that current exposures during the manufacture of 1,3-butadiene and its processing into polymers present an unreasonable risk of injury to human health, and EPA has determined that the risk may be reduced to a sufficient extent by action taken under the OSHAct. Therefore, pursuant to section 9(a) of TSCA, the Agency is issuing this report and is requesting OSHA to determine if the risk described in the report may be prevented or reduced to a sufficient extent by action taken under the OSHAct and, if so, to issue an order declaring whether the activities described in this report present the risk described. A response from OSHA to the Administrator of EPA is requested within 180 days of publication of this report in the *Federal Register*. EPA believes 180 days is sufficient time for OSHA to evaluate the scientific matters and policy requirements. In particular, OSHA will have to evaluate the data relating to significant risk and evaluate the technical and economic feasibility of control options in affected industries.

## II. Legal Authorities

TSCA provides EPA with broad authority to assess and regulate chemical substances in the environment, in the workplace, and in commercial products. Under section 6(a) of TSCA, EPA is authorized to impose regulatory controls if the Agency finds that there is reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance presents or will present an unreasonable risk of injury to human health or the environment.

To determine whether a risk is unreasonable, EPA balances the probability that harm will occur from the chemical substance under consideration against the social and economic costs to society of placing restrictions on the chemical. Specifically, as stated in section 6(c) of

TSCA, this conclusion incorporates consideration of:

1. The effects of the chemical substance on the health of humans.
2. The magnitude of human exposure to the chemical substance.
3. The benefits of the chemical substance for various uses.
4. The availability of substitutes for such uses.
5. The reasonably ascertainable economic consequences of regulation, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

The Agency realizes that no single mathematical formula can be used to calculate unreasonable risk, since the amount and nature of the information will differ in each case. Instead, EPA applies a general approach on a case-by-case basis, weighing quantitative information with qualitative factors, and applying generally accepted principles of responsible public health administration and prudent public policy.

Under section 9(a)(1) of TSCA, the Administrator is required to submit a report to another Federal agency when two determinations are made. The first determination is that the Administrator has reasonable basis to conclude that a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The second determination is that the unreasonable risk may be prevented or reduced to a sufficient extent by action taken by another Federal agency under a Federal law not administered by EPA. Section 9(a)(1) provides that where the Administrator makes these two determinations, EPA must provide an opportunity to the other Federal agency to assess the risk described in the report, to interpret its own statutory authorities, and to initiate an action under the Federal laws that it administers.

Accordingly, section 9(a)(1) requires a report requesting the other agency (1) to determine if the risk may be prevented or reduced to a sufficient extent by action taken under its authority, and (2) if so, to issue an order declaring whether or not the activities described in the report present the risk described in the report.

Under section 9(a)(2), EPA is prohibited from taking any action under section 6 or 7 with respect to the risk reported to another Federal agency pending a response to the report from the other Federal agency. There would be no similar restriction on EPA for any risks associated with a chemical

substance or mixture that is not within the section 9(a)(1) determinations and therefore not part of the report submitted by EPA to the other Federal agency.

The second agency may take one of five possible actions set out below. The Administrator may not take any action under section 6 or 7 with respect to such risk if the other agency either:

(1) Issues an "order" within the EPA deadline, stating that the activities EPA has described do not present the "unreasonable risk" EPA has attributed to them; or

(2) "initiates" within 90 days of its response to EPA action to "protect against" the risk identified by EPA.

On the other hand, EPA may take further action if the other agency either:

(a) Determines that its law does not authorize action to prevent or reduce the unreasonable risk to a sufficient extent; or

(b) explicitly defers to EPA despite the existence of adequate authority on its part (unless its own statutory authority precludes such action), presumably on the ground that action by EPA is preferable on practical or public policy grounds; or

(c) does nothing, in which case EPA, once the deadline has expired, remains free to act as before.

## III. Findings Under Section 9(a)

In this unit, EPA discusses the findings used to support its decisions to refer 1,3-butadiene to OSHA. Units A and B constitute a summary of the factors used to assess the potential risks to workers exposed to 1,3-butadiene. Details of the evidence used to estimate the risks from exposure to 1,3-butadiene, and of the conclusions reached based on that evidence, are presented in the EPA support document, "Assessment of Cancer Risks to Workers Exposed to 1,3-Butadiene During Production of 1,3-Butadiene Monomer and Production of Synthetic Rubbers, Plastics, and Resins." Units C and D constitute a summary of the benefits of the continued production and use of 1,3-butadiene, and the potential consequences of regulatory action. Units E and F present the conclusions with respect to the unreasonable risk determination and the determination that the risk can be reduced to a sufficient extent by OSHA.

In addition to the support document on occupational cancer risks developed by the Office of Pesticides and Toxic Substances (OPTS) to support referral to OSHA, the Agency's Office of Health and Environmental Assessment (OHEA) also prepared a hazard assessment.

"Mutagenicity and Carcinogenicity Assessment of 1,3-Butadiene" (Ref. 11). That document was developed primarily for use by the Agency's Office of Air and Radiation to support regulatory decision-making regarding possible listing of 1,3-butadiene as a hazardous air pollutant. Both documents focused primarily on the assessment of carcinogenic potential and concluded that 1,3-butadiene is a probable human carcinogen [Group B2]. The OPTS document includes a description of occupational exposures and a discussion of the potential cancer risks to workers. The two documents employ slightly different approaches to the quantitative risk assessment which is used to estimate human risk at low doses on the basis of the dose-response seen in the bioassay on mice. While the risks that are predicted using these two methodologies are somewhat different, these differences do not affect the referral decision. The final OHEA document (Ref. 11) incorporates in the quantitative risk estimation recently received data on absorption of 1,3-butadiene by mice. The result of this alternative methodology is to estimate a higher human risk than was previously estimated.

#### A. The Effects of the Chemical Substance on Health

In conducting risk assessments of suspected carcinogens, EPA generally evaluates the overall weight of evidence, including both primary and secondary evidence of carcinogenicity. As specified in the Agency's "Proposed Guidelines for Carcinogen Risk Assessments" (Ref. 10), primary evidence derives for long-term animal studies and available epidemiological data. Secondary or supplemental evidence includes the results of short-term tests, metabolic and pharmacokinetic studies, other relevant toxicological studies, and inferences deduced from chemical structure-activity relationships.

Based upon the weight of available evidence, EPA classifies 1,3-butadiene as a probable human carcinogen. The Guidelines cited above give this classification when:

Evidence of human carcinogenicity from epidemiological studies ranges from almost "sufficient" to "inadequate." To reflect this range, the category is divided into higher (Group B1) and lower (Group B2) degrees of evidence. Usually, category B1 is reserved for agents for which there is at least limited evidence of carcinogenicity to humans from epidemiological studies. In the absence of adequate data in humans, it is reasonable, for practical purposes, to regard agents for which there is sufficient evidence of carcinogenicity in animals as if they presented a carcinogenic

risk to humans. Therefore, agents for which there is inadequate evidence from human studies and sufficient evidence from animal studies (as 1,3-butadiene) would usually result in a classification of B2.

1. *Animal studies.* In assessing the cancer hazard posed to workers by 1,3-butadiene, EPA's conclusions rest primarily on the evidence of carcinogenicity from animal studies. 1,3-Butadiene has been shown to induce cancers at multiple sites in both sexes of two species of laboratory animals exposed at different dose levels. In addition, the animals were exposed via inhalation, the primary route of worker exposure to 1,3-butadiene. Further, tumors were induced in these animal species at exposure levels equal to or below the current OSHA workplace standard of 1,000 ppm, 8-hour time-weighted average (TWA).

In the rat and mouse, neoplastic response to 1,3-butadiene was considered to be biologically significant for several reasons. There were statistically significant increases in the incidence rates of many tumors observed in the treated mice and rats. For the rat, these included mammary fibroadenomas/carcinomas and thyroid follicular cell tumors in females, and Leydig cell adenoma and pancreatic exocrine tumors in males. In mice, the observed tumors included hemangiosarcomas of the heart, malignant lymphomas, alveolar/bronchiolar adenomas and carcinomas, and forestomach papillomas and carcinomas in males and females. In female mice, there were also hepatocellular adenomas/carcinomas, mammary gland acinar cell carcinomas, and ovary granulosa cell tumors. For several of these sites in the rat and mouse, the tumor response was dose-related. In both species, historically rare or uncommon tumors were observed. In the mouse, some tumors developed very early in the study, such as malignant lymphomas (week 20), hemangiosarcomas (prior to weeks 60-61), and hepatocellular tumors (prior to weeks 60-61). In both species, there was decreased survival in the treated animals. In the mouse, there was an especially strong response, with greater than 90 percent of the animals dying of tumors by weeks 60-61 of the planned 104-week study.

The evidence of carcinogenicity in animals has provided the basis for a quantitative assessment of risks to workers exposed to 1,3-butadiene.

2. *Epidemiological studies.* EPA has also given consideration to the available epidemiological studies on workers in synthetic rubber plants. Although these studies show increased mortality from

leukemia and lymphatic and hematopoietic system neoplasms, the Agency has concluded that they are generally inadequate to assess cancer mortality in the exposed populations because of study design limitations. Insufficient follow-up, low statistical power to detect moderate elevations of lymphatic/hematopoietic system neoplasm or leukemia risk, the lack of quantitative exposure estimates, and the inability to separate compounding exposures were the major limitations of the epidemiological studies. Therefore, these studies do not establish a link between 1,3-butadiene and human carcinogenicity, but neither do they show the absence of such a link.

3. *Secondary evidence.* The secondary evidence supporting the potential carcinogenicity of 1,3-butadiene in humans comes from studies of absorption, distribution, metabolism, and short-term assays. These studies show that 1,3-butadiene is readily absorbed by animals and humans via inhalation and that in animals it is distributed to many organs and tissues. Testing of 1,3-butadiene indicates that it is an indirect gene mutagen in bacteria, requiring metabolic activation to mutagenic intermediates. 1,3-Butadiene feedstock containing 40-69 percent of this chemical is a chromosome mutagen *in vivo*. There is evidence from metabolic studies indicating that 1,3-butadiene is converted to reactive epoxide metabolites which are direct-acting mutagens in several test systems (*in vitro* and *in vivo*) and which are DNA alkylators. There is also evidence that these metabolites may be potential carcinogens in animals. There is, however, insufficient knowledge of the metabolism and pharmacokinetics of 1,3-butadiene in humans and of the mechanism of cancer induction in animals to predict the specific mechanism of carcinogenicity in animals and humans or to predict a most likely target site for carcinogenesis in humans. No information was found on the potential carcinogenicity of chemical compounds considered to be structurally analogous to 1,3-butadiene.

4. *Summary.* The overall weight of currently available evidence indicates that 1,3-butadiene is a probable human carcinogen [Group B2] based on sufficient evidence in animals, including metabolism and short-term tests, and on inadequate epidemiological evidence.

#### B. Human Exposure And Risk

1. *Exposure information.* The Agency has reviewed a number of surveys of air concentrations of 1,3-butadiene to which workers are exposed in plants that

produce the monomer and in plants that process it into various polymers. The air monitoring data were obtained from various organizations, including the Chemical Manufacturers Association, the International Institute of Synthetic Rubber Producers, the United Rubber Workers International Union, the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, and several individual chemical and rubber companies.

The data compiled from these various sources indicate that from 480 to 740 workers in monomer production plants and from 4,800 to 7,500 workers in polymerization plants are exposed to 1,3-butadiene. In the monomer production plants, 9 job categories with exposed workers have been identified: non-technical laboratory technician, technical laboratory analyst, operator, warehouse worker, stillman, operator's helper, foreman, maintenance man, and pumper/loader. In polymerization plants, 12 job categories with exposure to 1,3-butadiene have been established: tank-car unloader, reactor operator, stripper-column operator, coagulation operator, warehouse worker, laboratory analyst, foreman/engineer, maintenance worker, vessel cleaner, baler/packer, dryer operator, and blend-tank operator.

The levels of inhalation exposure for each job category were determined by the use of personal monitoring devices. Although not all of the sampling and analysis surveys were performed in accordance with the procedure developed by the National Institute for Occupational Safety and Health (NIOSH), the results obtained by the various methods were comparable to the results obtained by the NIOSH procedure. The results of these surveys indicated a wide range of 1,3-butadiene exposure to workers; typical workday exposures ranged from less than 1 part per million (ppm) to levels as high as 500 to 1,000 ppm in a few instances. Based on this survey information, EPA determined a range of hypothetical exposure profiles for the various job categories. These exposure profiles were used in the preparation of the quantitative risk assessment.

The Agency's exposure assessment is presented in detail in the support documents entitled, "Assessment of Occupational Exposure Data on 1,3-Butadiene in Plants Producing Synthetic Rubbers, Plastics, and Resins" and "Control of Occupational Exposure to 1,3-Butadiene at Monomer Production Facilities." These documents describe the various assumptions used by the

Agency and also indicate the limitations of the exposure assessment.

2. *Methodology used for estimating cancer risk to workers.* Human cancer risks from exposure to 1,3-butadiene were estimated by modelling the results of the long-term mouse oncology study (Ref. 9) mathematically to predict carcinogenic response at doses lower than the experimental dose levels. The mouse oncology study was chosen for the modelling for several reasons. A major consideration was that the mouse appeared to be the more sensitive of the two species. To estimate the cancer risk, pooled tumor data were used, which give a measure of general, overall response to 1,3-butadiene. Estimates of cancer risk were based on the data for male mice, because they had a higher cancer response rate than females. This response rate consequently gave higher extra lifetime risks at low doses.

The mathematical modelling technique consisted of a single-stage model, which yielded upper 95 percent confidence limits on risk estimates. These were equivalent to risk estimates obtained by the linearized multistage modelling procedure recommended in the Agency's "Proposed Guidelines for Carcinogenic Risk Assessment" (Ref. 10).

To characterize the cancer risk to workers exposed to 1,3-butadiene, the Agency used the exposure information obtained for the various job categories in monomer and polymer production plants to estimate lifetime average daily dose (LADDs).<sup>1</sup> For the calculation of LADDs, the Agency assumed that (1) humans live for an average of 70 years, (2) mice and humans absorb the same percentage of inhaled 1,3-butadiene, and (3) the workers are exposed during 40 years of employment. The risk estimates used by the Agency are the 95 percent upper confidence limits of extra lifetime risk to workers based on pooled tumor data for mice.

The risk assessment methodology used by the Agency, together with the various assumptions and inherent limitations, is described in detail in the support document, "Assessment of Cancer Risks to Workers Exposed to 1,3-Butadiene During Production of 1,3-Butadiene Monomer and Production of

Synthetic Rubbers, Plastics, and Resins."

3. *Cancer risk estimates.* When the above risk assessment methodology was applied to the hypothetical exposure profile developed for each of the job categories identified in monomer production and polymerization plants, the resulting upper-limit risk estimates varied within each job category. For some job categories, the estimated individual risk ranged from 1 lifetime excess cancer incidence in 1,000 workers to 1 incidence in 1 worker. For some other job categories, the range of the estimated risk was from 1 in 10,000 to 1 in 10. The magnitude of the estimated risk to a worker depended on the exposure range in which he was located within a particular job category. For example, from 800 to 1,200 reactor operators were estimated to be exposed in polymerization plants for 8 hours per day, 240 days per year, over a period of 40 years. Seventy-eight percent of these reactor operators were in the 1,3-butadiene exposure range of non-detectable levels to 5 ppm. Within this single exposure range, the estimated cancer risk varied according to the actual exposure level: 1 in 1,000 at 0.1 ppm, 1 in 100 at 1 ppm, and 1 in 10 at 5 ppm. For the 22 percent of the reactor operators who were in the higher exposure ranges, the estimated individual cancer risk varied from 1 in 10 at 10 ppm to 1 in 1 at 25 ppm and above. About 7 percent of the reactor operators were exposed to 1,3-butadiene at levels higher than 25 ppm.

Another way of expressing the cancer risk from 1,3-butadiene in monomer and polymer production plants is to calculate the extra lifetime cancer incidence in worker populations (i.e., population risk) in these two industry segments. The Agency has performed such calculations, as shown in the support document entitled, "Estimates of Cancer Incidence in Workers Exposed to 1,3-Butadiene." The results of the obtained estimates are summarized below.

a. *Monomer production plants.* The estimated number of extra lifetime cancer cases (population risk) was calculated by multiplying the extra lifetime individual risks by the number of workers for each of the exposure ranges of the nine job categories. For the combined population of 480 to 740 workers, the estimated number of lifetime cancer cases caused by 40 years of exposure to 1,3-butadiene ranged from 22 to 80. These numbers reflect the range in the number of workers and the range of individual risks depending on exposure levels.

<sup>1</sup> The LADD is the amount of chemical that a worker is expected to absorb over his or her working career, divided by the expected lifetime of the worker and by the worker's body weight. This number is used to relate the expected daily dose that a worker received to the dose that the test animals received in the oncology study, and permits the comparison of observed tumor rates in test animals with possible tumor rates in exposed workers.

b. *Polymerization plants.* For this segment of the industry, the number of extra lifetime cancer cases was estimated to be in the range of 148 to 838, in a total population of 4,800 to 7,500 workers.

It should be emphasized that the extra lifetime individual risk estimates upon which the Agency's calculations are based represent upper-limit risks. Although these estimates are considered to be plausible upper bounds, indicating the upper end of the range of cancer risks that might be expected for the workers, the actual risks may be lower.

#### C. The Benefits of 1,3-Butadiene

EPA estimates that the current volume of 1,3-butadiene production in the U.S. is approximately 3 billion pounds per year, with an industry capacity of about 4 billion pounds. Most of this important industrial chemical is produced as a byproduct of ethylene manufacture and used captively for the production of rubbers, plastics, resins, fibers, and other polymeric products.

The major polymers made from 1,3-butadiene include styrene-butadiene (SBR) elastomers and latexes, polybutadiene elastomers, polychloroprene, nylon fibers and resins, acrylonitrile-butadiene-styrene (ABS) resins, acrylonitrile-butadiene (nitrile) rubbers, and ethylene-propylene-diene modification (EPDM) elastomers. These polymer uses of butadiene were estimated to account for over 95 percent of all domestic butadiene consumption in 1981.

In addition to its major uses, 1,3-butadiene is employed in a number of minor polymer applications, including modified polybutadiene as propellant binders, specialty copolymer resins and latexes for paints, coatings and adhesive applications, and hydrogenated butadiene-styrene polymers used as lubricating oil additives.

1,3-Butadiene is also used as an intermediate in the production of a number of non-polymers, including the agricultural fungicides Captan and Captofol, anthraquinone dyes, and the industrial extraction solvent Sulfolane.

Although technically suitable substitutes are available for most of the major uses of 1,3-butadiene, the cost of replacing this large-volume chemical is very high, as shown in the support document, "1,3-Butadiene Use and Substitutes Analysis."

#### D. The Reasonably Ascertainable Consequences of Potential Regulation

This unit concentrates on the regulatory measures that would likely be used to control exposure in the workplace. As discussed below, EPA

has determined that workplace control methods appear to be both technologically and economically feasible to significantly reduce 1,3-butadiene exposures. Workplace control methods could include engineering controls, such as installation of dual mechanical seals, or the use of personal protective equipment, such as respirators. The technology for effective engineering controls is known and currently practiced in parts of the 1,3-butadiene industry. EPA's estimated exposure reductions are based on the available monitoring information and the hypothetical exposure situations developed in the risk assessment.

1. *Engineering controls.* Effective, yet relatively inexpensive engineering controls consist of installation of dual mechanical seals to prevent 1,3-butadiene leaks from pumps and compressors. These engineering controls have proven effective in reducing workers exposures in the vinyl chloride industry. Fugitive emissions from pumps, compressors, transfer lines, and sampling equipment can be controlled by relatively standardized engineering designs.

Complete enclosure and industrial ventilating systems may offer two other methods for reducing occupational exposures to a toxic chemical such as 1,3-butadiene. For the latter, either local exhaust ventilation or higher-volume general dilution air systems could be used; however, attention should be given to safeguarding the quality of the ambient air. Additionally, in the 1,3-butadiene monomer manufacturing industry the facilities are large outdoor plants where in most cases general mechanical exhaust ventilation and local exhaust ventilation are not feasible.

2. *Personal protective equipment and industrial hygiene practices.* Personal protective equipment and industrial hygiene practices can be effective ways to protect the worker from exposure to 1,3-butadiene in certain situations (e.g., protective gloves to prevent dermal contact with the liquefied chemical). The use of personal protective equipment, such as NIOSH-approved respirators, may be less effective than engineering controls due to the physical layout of the plants where 1,3-butadiene is manufactured and processed. Consequently, the Agency's estimate of the cost of effective workplace controls is based on engineering controls.

3. *Cost of controls.* The EPA has prepared a preliminary economic analysis of the costs associated with the imposition of workplace engineering controls on both the manufacturing and the processing of 1,3-butadiene. The

support document "Regulatory Impact Analysis of 1,3-Butadiene" presents fully the methodology, data, and assumptions used in arriving at the costs. In summary, the imposition of workplace controls that should be capable of achieving workplace exposures of less than 1 ppm would result in estimated incremental costs of \$118,000 to \$320,000 per facility. On an annualized cost basis, the costs would range from \$20,000 to \$53,000 per plant, assuming a 10 percent discount rate over a 10-year period. Given the large volume of 1,3-butadiene produced annually, the potential impact on price of requiring engineering controls would not be significant.

#### E. Unreasonable Risk Determination

Available evidence indicates that 1,3-butadiene causes cancer in mice and rats and is a probable human carcinogen. Using the results of the mouse oncology study, the Agency performed mathematical modelling to estimate the cancer risk to workers in plants that produce 1,3-butadiene and process this chemical into polymers. Based on available workplace monitoring data, the upper-bound lifetime risk to workers in these plants is estimated to be in the range of 1 in 1 to 1 in 10,000, resulting in up to 900 extra lifetime cases of cancer.

The imposition of more effective engineering controls appears to be capable of reducing all workplace exposures to less than 1 ppm, thereby reducing the cancer risk to 1 in 100 or less and the extra lifetime cases of cancer to less than 100. The Agency's best estimate of the industry-wide total costs of the improved engineering controls is in the range of \$8 million to \$21 million, expressed in current dollars. (On an annualized cost basis, these engineering controls would cost from \$1.3 million to \$3.4 million per year, calculated over a 10-year period at a 10 percent discount rate.) Accordingly, up to 800 cancers could be avoided over a 40-year period at a total cost of \$10,000 to \$26,000 per cancer case avoided. Thus, through relatively inexpensive engineering controls, which are already in place at some 1,3-butadiene manufacturing and processing facilities, about 90 percent of the cancer risk may be eliminated. Further risk reduction through the use of more stringent engineering controls may be possible, but it appears that plant redesign would be required, thus resulting in a significantly higher cost. The Agency does not anticipate that the cost of the controls will have any adverse impact on the national economy or on small businesses. EPA therefore has

reasonable basis to conclude that current exposures during the manufacture of 1,3-butadiene and its processing into polymers present an unreasonable risk of injury to the health of exposed workers.

*F. Unreasonable Risk May Be prevented or Reduced to a Sufficient Extent by Action Taken under OSHA*

A significant concern about human exposures to 1,3-butadiene relates to inhalation of this chemical in the workplace. The OSHA is the primary statute for protecting the health and safety of workers, and, as such, provides broad authorities to achieve this objective. As discussed in Units C and D, a revised workplace standard may reduce unreasonable risks from the manufacture and processing of 1,3-butadiene to a sufficient extent. The requirement of such a revised workplace standard is clearly within the statutory authority of OSHA. Furthermore, OSHA has experience and expertise in enacting and enforcing these types of regulations. Therefore, EPA has determined that the unreasonable risk of injury to the health of exposed workers may be reduced or prevented by actions taken by OSHA under the Federal law it administers.

**IV. Conclusions**

Based upon the information in this report, and the supporting documents from which the information was extracted, the Administrator of EPA has concluded that the manufacture and processing of 1,3-butadiene, as currently practiced, present an unreasonable risk of cancer to workers. The Administrator has also determined that such risk may be eliminated or reduced to a sufficient extent by actions taken under the OSHA. Therefore, under requirements of sec. 9 of TSCA, the Agency is requesting OSHA to:

1. Determine if the risk described in this report may be prevented or reduced to a sufficient extent by action taken under the OSHA; and,
2. If so, issue an order declaring whether or not the risk described in this report is unreasonable.

We ask that OSHA respond to our request for the determination and order within 180 days of the date of publication of this notice in the **Federal Register**. In accordance with section 9, the response from OSHA must be accompanied by a detailed statement of OSHA's findings and conclusions, and must be published in the **Federal Register**.

**V. Public Record**

EPA established a record for this notice (docket number OPTS-91002).

The record for the ANPR (OPTS-62034) and for the sec. 4(f) notice (OPTS-48502) are included in the new record. Nonconfidential information along with a complete index is available for inspection in the Office of Toxic Substances reading room from 8 a.m. to 4 p.m. Monday through Friday, except legal holidays. The Agency also maintains a record of confidential information that is not part of the public record. The Public Information Office is located in Rm. E-107, 401 M Street SW., Washington, D.C. 20460. The record includes basic information considered by the Agency in developing the ANPR and this notice. The Agency will supplement the record with additional information as it is received.

**A. References**

- (1) Chemical Manufacturers Association (CMA). Comments of the CMA's Butadiene Program Panel to EPA's Advance Notice of Proposed Rulemaking (ANPR). July 16 and August 29, 1984.
- (2) E.I. du Pont de Nemours and Company. Comments on 1,3-Butadiene, Initiation of Regulatory Action. July 16, 1984.
- (3) International Institute of Synthetic Rubber Producers, Inc. (IISRP). Comments on the ANPR. July 13 and August 29, 1984.
- (4) IISRP. The Toxicity and Carcinogenicity of Butadiene Gas Administered to Rats by Inhalation for Approximately 24 Months. Final report, prepared by Hazleton Laboratories Europe Ltd., Volumes 1-4, dated November 1981.
- (5) Natural Resources Defense Council, Inc. (NRDC). Comments of NRDC on Advance Notice of Proposed Rulemaking Governing Initiation of Regulatory Action on 1,3-Butadiene. July 16, 1984.
- (6) Polysar Limited. Comments on the ANPR. June 28, 1984.
- (7) Rubber Manufacturers Association (RMA). Comments on the ANPR. July 16, 1984.
- (8) Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA). Comments on the ANPR. July 16, 1984.
- (9) U.S. Department of Health and Human Services, PHS, NIH, National Toxicology Program (NTP). NTP Technical Report on the Toxicology and Carcinogenesis Studies of 1,3-Butadiene (CAS 106-99-0) in B6C3F<sub>1</sub> Mice (Inhalation Studies). August 1984.
- (10) U.S. EPA, Office of Research and Development, Office of Health and Environmental Assessment. Proposed Guidelines for Carcinogenic Risk Assessments. Published in the **Federal Register** of November 23, 1984 (49 FR 46294).
- (11) U.S. EPA, Office of Research and Development, Office of Health and Environmental Assessment. Mutagenicity and Carcinogenicity Assessment of 1,3-Butadiene. August 1985.

**B. Support Documents**

- (1) USEPA, OPTS, ECAD. Assessment of Cancer Risks to Workers Exposed to 1,3-Butadiene During Production of 1,3-Butadiene Monomer and Production of Synthetic

Rubbers, Plastics, and Resins. January 31, 1985.

(2) USEPA, OPTS, ECAD. Estimates of Cancer Incidence in Workers Exposed to 1,3-Butadiene. Supplement to (1) above. February 4, 1985.

(3) USEPA, OPTS, EED. Memorandum and Technical Support Document from M.P. Halper, "1,3-Butadiene Quantitative Risk Assessment: Dose-Response Investigations." November 30, 1984.

(4) USEPA, OPTS, ETD. Assessment of Occupational Exposure Data on 1,3-Butadiene in Plants Producing Synthetic Rubbers, Plastics and Resins. December 1984.

(5) USEPA, OPTS, ETD. 1,3-Butadiene Use and Substitutes Analysis. August 10, 1984. Prepared by ICF Inc.

(6) USEPA, OPTS, ETD. Control of Occupational Exposure to 1,3-Butadiene at Monomer Production Facilities. February 1985. Prepared by PEDCO Environmental, Inc.

(7) USEPA, OPTS, ETD. Production and Utilization of 1,3-Butadiene: Potential Exposure to Workers and the General Population. September 13, 1983. Prepared by Environ Corporation.

(8) USEPA, OPTS, ETD. Regulatory Impact Analysis of 1,3-Butadiene. April 15, 1985.

(9) USEPA, OPTS, ETD. Worker Exposure to 1,3-Butadiene in the Plastics and Rubber Industry. February 1985. Prepared by PEI Associates, Inc.

Copies of all references and support documents are available for inspection in Rm. E-108, at the EPA address given above. OSHA's response to EPA will also be inserted in the public record upon its receipt.

Dated: October 1, 1985.

Lee M. Thomas,  
Administrator.

[FR Doc. 85-24271 Filed 10-9-85; 8:45 am]

BILLING CODE 6560-59-M

**FEDERAL COMMUNICATIONS COMMISSION**

**Declaratory Ruling; Order Extending Time**

**AGENCY:** Federal Communications Commission.

**ACTION:** Order extending time.

**SUMMARY:** The Order grants the motions of several parties to file their pleadings late and extends the date on which reply comments are due in the proceeding. *Declaratory Ruling on the Application of section 2(b) of the Communications Act of 1934 to Bell Operating Companies*, FCC 85-320 (released June 20, 1985), 50 FR 27053 (July 1, 1985). The proceeding began with a declaratory ruling by the Commission that the divested Bell Operating Companies remained fully subject carriers. It established procedures by which parties