

LAW OFFICES
BEVERIDGE, FAIRBANKS & DIAMOND

ONE FARRAGUT SQUARE SOUTH
WASHINGTON, D. C. 20006

TELEPHONE
(202) 638-7800

CARL EARDLEY
OF COUNSEL

CABLE ADDRESS
"INDLAW"

HENRY L. DIAMOND
RICHARD M. FAIRBANKS, III
ALBERT J. BEVERIDGE, III
GARY H. BAISE
A. JAMES BARNES
HAROLD HIMMELMAN
CHRISTOPHER H. BUCKLEY, JR.
KEVIN M. FOLEY
JONATHAN Z. CANNON
ANDREW E. MISHKIN
CHARLES A. PATRIZIA
SCOTT W. BOWEN

16 December 1977

Joseph E. Hadley, Jr., Esquire
Keller & Heckman
Suite 1000
1150 17 Street N.W.
Washington, D.C. 20036

Dear Joe:

This letter will update you regarding EPA's plans regarding the cancer policy review suggested by the Administrator of EPA in his meeting with the representatives of SPI.

The Environmental Defense Fund filed a petition on November 7, 1977 requesting that EPA promulgate a new cancer policy and regulations. This petition and the Amendments to the National Emission Standard for Vinyl Chloride have caused the staff at EPA to develop a schedule to review EPA's present cancer policy.

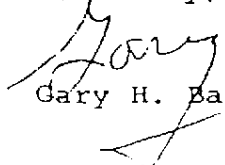
EDF's counsel will be meeting with EPA staff in Research Triangle Park some time during December or the first part of January. After this meeting a determination will be made as to whether EDF will meet with the Administrator of EPA as requested in the November 7th petition.

Within a couple of weeks after the meetings, EPA will seek public comments regarding what EPA's cancer policy should be. We are advised that EPA will not be publishing EDF's proposal. This information comes from attorneys in the EPA General Counsel's office. The Federal Register notice will call for public comment and set a public hearing date. EPA expects substantial comment because of the present OSHA action.

If Mr. Costle does not issue a final decision regarding the Vinyl Chloride Amendments until a final decision is made regarding an EPA cancer policy, the PVC Safety Group could be facing a substantial delay. This delay, and this is rank speculation, could take up most of next year. We have spoken to a number of individuals in EPA and most of them believe this process could take the Agency through July or later before a decision is final from Mr. Costle.

If you have any questions, please advise.

Cordially,


Gary H. Baise

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of the permits provided for an evaluation of the product on rice to repel various black bird species feeding on heading rice. The permit allowed use of 4,406 pounds of the product and it expires Jan. 1, 1979.

The other Mobay permit calls for use of 1,350 pounds of the bird repellent on blueberries to evaluate control of the blueberry maggot, blueberry case beetle and blueberry flea beetle and to repel various depredating bird species attacking ripening blueberries. The permit expires Sept. 12, 1978.

The third Section 5 permit was issued to Uniroyal Chemical and allows the use of 171 pounds of the herbicide 2,3-dihydro-5,6-dimethyl-1,4-dithiin 1,1,4,4-tetra-oxide on cotton and potatoes to evaluate its use as a defoliant and desiccant. The permit is effective until Sept. 29, 1978.

The three DBCP documents relating to suspension, conditional suspension and cancellation of DBCP uses were published in the Nov. 3 Federal Register.

A notice on the status of the rebuttable presumption against registration on three nitrosamine-containing pesticides--Treflan, Trysben, and Benzac--appeared in the Nov. 2 Federal Register (See Oct. 19, Page 17).

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EDF AIR CARCINOGENS PETITION SEEKS EPA POLICY SIMILAR TO OSHA PROPOSAL

The Environmental Defense Fund (EDF) this week petitioned the Environmental Protection Agency to begin a rulemaking proceeding to establish a policy which would expedite control of airborne carcinogens. The policy was supposed to be part of EDF's petition asking EPA to control air emissions of benzene (See March 16, Page 4).

The proposal, modeled after one published for comment by the Occupational Safety and Health Administration (OSHA), would have EPA categorize substances as "confirmed," "probable," or "possible" carcinogens. Like the OSHA proposal (See Oct. 5, Page 11), placement of a substance into a certain category could be rebutted, issues open for discussion in such an administrative action would be limited, and if the rebuttal were unsuccessful, certain regulatory actions automatically would be triggered.

In the case of a successful EPA classification of a substance as a "confirmed" carcinogen, EPA would be required to list the substance as a hazardous air pollutant under Section 112 of the Clean Air Act, the EDF proposal says. One hundred and eighty days after the listing, EPA would have to propose regulations which would either prohibit emissions of the substance or prescribe "best available control technology" (BAT).

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As provided in the OSHA proposal, the EDF scheme would allow prohibitions of emissions if there were substitutes for the substance or for whatever caused the emissions. If BAT were prescribed, the EDF proposal says, a schedule would have to be worked out "which would ultimately eliminate emissions." This is the intent of EDF's action in the vinyl chloride case (See Sept. 14, Page 2).

If a substance were classified as either a "probable" or "possible" carcinogen, and the classification could not be rebutted, EPA would have to order additional tests under Section 4 of the Toxic Substances Control Act (TSCA) or pay for the tests itself, the EDF proposal says.

The proposed policy would have EPA prescribe standards for any tests which it ordered, did itself or had done. After the tests were completed, EPA would reclassify the substance. The EDF proposal says that studies aimed at changing "possible" carcinogens to "probable" carcinogens must be completed within one year of classification of a substance as a Category III or "possible" carcinogen. Studies aimed at classifying "possible" carcinogens as "confirmed" ones would have to be completed within three years, the EDF proposal says.

EDF Trigger for "Confirmed" Carcinogens is More Sensitive Than OSHA's

According to the EDF proposal, a substance should be classified as a Category I or "confirmed" carcinogen if it or one of its degradation products:

"(P)roduces or induces a statistically significant increase in benign or malignant neoplasms, tumors, or a combination thereof, or causes a statistically significant decrease in the latency period between exposure and onset of benign or malignant neoplasms, tumors, or some combination of the two in (i) humans; (ii) a single experiment on one or more mammalian test species, if the results are reproducible."

The classification could also be made "if the Administrator finds other evidence to be sufficiently probative of carcinogenicity," the proposal says.

The EDF proposal differs from OSHA's in that OSHA's proposal says a positive result in a single test on one mammalian species is sufficient evidence if the results "have been replicated" in an independent, separate study using the same species. EDF says only that the positive results must be "reproducible." Also, OSHA's proposal does not mention a decreased latency period as a trigger.

A substance would be a "probable" carcinogen, the EDF proposal says, if it or one of its degradation products:

"(1) produces or induces a suggestive increase in benign or malignant neoplasms, tumors, or a combination thereof; or causes a suggestive decrease in the latency period between exposure and onset of benign or malignant tumors, neoplasms, or some combination of the two in humans or a single experiment on one or more mammalian test species; or

"(2) produces a positive result in one or more short term tests, including tests for: (i) mutagenicity in *Salmonella typhimurium*; (ii) in vitro mammalian cell transformation; or (iii) any other short term test or tests designated by the Administrator; or

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"(3) is determined by the Administrator to be a Probable Carcinogenic Substance on the basis of evidence which he finds sufficiently probative."

OSHA's justification for a Category II substance would be a positive result "in an unreplicated experiment in a single mammalian species" or other evidence "sufficient" to justify such a classification.

A substance would be a Category III or "possible" carcinogen, the EDF proposal says, if it or one of its degradation products:

"(1) belongs to a class of compounds that regularly displays carcinogenic activity, including (i) polycyclic aromatic hydrocarbons, (ii) chlorinated hydrocarbons, (iii) nitrosamines, (iv) aromatic amines, (v) any other class designated by the Administrator;

"(2) contains an active chemical moiety that regularly displays carcinogenic activity;

"(3) produces a positive result in any short term test or test designated by the Administrator;

"(4) is determined by the Administrator to be a Possible Carcinogenic Substance on the basis of any evidence he finds probative."

Among other differences, OSHA's proposal would not attempt to rely on structural similarities among compounds for purposes of classification.

EDF Wants NCI Opinion on Whether Positive Results are Meaningful

According to the EDF proposal, a classification of a substance as either Category I or II could be rebutted if both the EPA Administrator and the Director of the National Cancer Institute (NCI) conclude that a positive result:

"(1) was caused by physical induction, in that the appearance of the neoplastic effect occurred only at the site of administration, or

"(2) was obtained by use of a method of exposure wholly unrelated to circumstances of expected human exposure, or

"(3) is, in some demonstrable way, scientifically inadequate as proof of carcinogenicity. Such determination will be published in the Federal Register."

This is similar to OSHA's proposal.

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Issues to be addressed at the hearing on a substance's classification, the EDF proposal says, would be limited to:

"(a) whether the substance has been correctly classified according to the evidentiary requisites for the relevant category;

"(b) the scientific adequacy of evidence upon which the Administrator is basing the classification decision;

"(c) the availability, safety, and technological and economic feasibility of employing substitutes for the material or process which causes a Category I Confirmed Carcinogenic substance to be emitted into the atmosphere;

"(d) the lowest level of emissions that can now be reached, using best available technology, for substances listed as Category I Confirmed Carcinogenic Substances;

"(e) the lowest level of emissions that can be reached in the future using foreseeable technology for substances determined to be Category I Confirmed Carcinogenic Substances."

According to EDF attorney Robert Rauch, EPA "has failed to move against even a small fraction of the chemicals which may pose a cancer risk to humans. In its seven-year history, EPA has issued regulations for only four hazardous pollutants under §112 of the Clean Air Act and has just recently listed a fifth (benzene). The Mitre Corporation, on the other hand, has identified 600 organic air pollutants which may pose a threat to human health. Over 100 of them are suspected of causing cancer. Unless drastic changes are made, the Agency will never even get close to solving the problem."

ETHYLENE DICHLORIDE APPEARS TO BE POSITIVE IN CANCER INSTITUTE BIOASSAY

Ethylene dichloride (EDC), one of the twenty highest volume chemicals in the U.S., is a carcinogen, according to preliminary results from a National Cancer Institute (NCI) bioassay.

According to the National Occupational Hazard Survey conducted by the National Institute for Occupational Safety and Health (NIOSH), about two million U.S. workers are exposed to EDC full or part-time, and "98.2% of the exposure are not controlled."

NIOSH sources say that of the 7.9 million pounds of EDC produced in the U.S. in 1975, 75% were used to produce vinyl chloride. Also, a March 1976 NIOSH criteria document on EDC, which did not list cancer as an effect, said at least 29 U.S. firms use EDC as an ingredient in at least 45 fumigant-insecticide products.

According to NIOSH, 36 U.S. firms put EDC into mixes with ethylene dibromide (EDB), and the combination is used as an "anti-knock" mixture for leaded gasoline. EDC also is used to formulate degreaser compounds and certain rubber cements, NIOSH said.

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The 78-week NCI test, conducted by Hazleton Laboratories America, Inc., was a gastric intubation test involving rats and mice. According to an Experimental Design Group Status Report dated Nov. 8, 50 male rats exposed daily to an average of 50-75 milligrams EDC per kilogram of body weight, 20 developed malignant tumor. Six of the animals had hemangiosarcomas of the spleen and three had squamous cell carcinomas of the stomach.

Of 50 male rats exposed daily to 100-150 mg/kg, again, 20 developed tumors, nine of which were hemangiosarcomas of unnamed internal organs.

In a group of 20 male control rats receiving corn oil by gastric intubation rather than EDC, only four were tumor-bearing, the report said, while among 20 male rats which were not treated at all, six had tumors.

Female rats receiving the higher dose appeared to exhibit a statistically significant excess of adenocarcinomas of the mammary glands.

According to the report, male mice in the test appeared to have a statistically significant excess of carcinomas of the liver, while female mice appeared to have excesses of mammary gland and stomach tumors.

The Environmental Protection Agency, which recently got word of the preliminary NCI results, now is doing a hazard assessment on the chemical and is trying to determine if adequate monitoring data are available.

An EPA official said that in terms of stomach tumors, EDC did not look to be as potent a carcinogen as EDB (See Oct. 26, Page 14). The time-to-tumor ratio for EDB was shorter than EDCs, he said, and EDB produced more stomach cancers than did EDC.

He also said that EPA's regulatory response must take into account that NCI's test used gastric intubation, while exposures to the general environment probably involve inhalation.

The NCI test on EDC has not yet been forwarded to NCI's Clearinghouse for review. Another name for EDC is 1,2-dichloroethane; CAS number is 107062.

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PESTICIDE-NITROSAMINE CHEMISTRY DATA FILING DATE TO BE EXTENDED BY EPA

Apparently responding to numerous comments from industry asserting that the original 90 day filing time requirement for pesticide-nitrosamine analytical chemistry data was too short, the Environmental Protection Agency (See Oct. 26, Page 2) has decided to provide two compliance options: (1) submission of the analyses data within a total of 180 days of Sept. 29, the date the requirement was published in the Federal Register or (2) within the 180 days filing a plan, including an intended date for getting the analyses data to EPA.

The EPA decision will alleviate one of the main worries expressed by industry representatives commenting on the requirements but they have also pointed to

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(202) 638-7800

CARL EARDLEY
OF COUNSEL

CABLE ADDRESS
"INDLAW"

15 December 1977

Joseph E. Hadley, Jr., Esquire
Keller & Heckman
Suite 1000
1150 17 Street N.W.
Washington, D.C. 20036

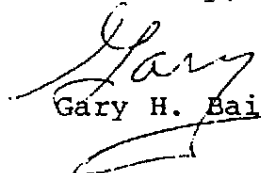
Dear Joe:

Enclosed is a proposed radiation notice from
the Federal Register dated November 30, 1977.

Please note the risk analysis discussion on
page 60957. Once again the Administrator is saying
that a single risk must be viewed from the overall
perspective of the costs and benefits. The Agency
is continuing to adopt the approach set forth in the
Vinyl Chloride Standard.

If you have any questions, please advise.

Cordially,


Gary H. Baise

Enclosure
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the loss of the fruit-bearing area, the losses are not confined to one year. Loss due to fire blight is compounded by the loss of large sections of an established tree; in some cases, whole trees might be lost. Once fire blight has gotten out of the control of the grower, several years are involved to bring the pear orchard back into production. Post-harvest sprays can be an important phase of fire blight control, since the bacterium overwinters on the host in cankers and attacks the blossoms in the spring.

Under epidemic conditions, 10 to 15% of the bearing surface of an orchard may be lost. Depending on the normal yield of the orchard, this could result in a loss ranging from 1/4 to 3 tons of pears per acre. Approximately 6,000 to 9,000 acres of pears are expected to have economic loss due to fire blight during the 1977 season. The Applicant estimated that, based on an average loss of one ton per acre, this represents a monetary loss of up to \$900,000 (current price approximately \$100/ton to the grower). Failure to control the disease will extend this loss to subsequent years. To this can be added the cost of bringing an orchard back to normal production by replacing dead or dying trees and cutting out infected wood.

After reviewing the application and other available information, EPA has determined that (a) a pest outbreak of fire blight on pears has occurred; (b) there is no pesticide presently registered and available for use to control fire blight in Washington State; (c) there are no alternative means of control, taking into account the efficacy and hazard; (d) significant economic problems may result if the fire blight is not controlled; and (e) the time available for action to mitigate the problems posed is insufficient for a pesticide to be registered for this use. Accordingly, the Applicant has been granted a specific exemption to use the pesticide noted above until October 31, 1977, to the extent and in the manner set forth in the application. The specific exemption is also subject to the following conditions:

1. The Myco Shield Brand of Pfizer Agricultural Terramycin, containing the calcium complex of oxytetracycline, is authorized at a dosage rate of 50 to 100 gallons of a 200 ppm spray solution. Up to 27,000 pounds of product may be used;

2. Up to 9,000 acres of pears in counties east of the crest of the Cascade Mountains may be treated. Treatment is authorized only after Washington State pathologists determine that streptomycin resistant strains of *Erwinia amylovora* are present in a given growing area;

3. Up to three post-harvest applications may be made. No application will be made to any block of trees until all fruit in that block has been harvested;

4. Application will be made with ground sprays and only by State-licensed commercial or certified private applicators. Applicators must wear protective clothing and respirators;

5. Workers may not enter orchards treated with terramycin until foliage is dry;

6. Applications must not be made near highly populated areas, hospitals, and areas where food or water may be contaminated;

7. A residue level of oxytetracycline in or on pears not exceeding 0.1 ppm has been deemed adequate to protect the public health. The Food and Drug Administration, U.S. Department of Health, Education, and Welfare, has been advised of this action;

8. The EPA shall be immediately informed of any adverse effects resulting from the use of terramycin in connection with this exemption; and

9. The Applicant is responsible for ensuring that all provisions of this exemption are followed, and that records are kept of the amount of terramycin sold to growers for the purpose of fire blight control. A final report must be submitted by October 31, 1978, which summarizes the results of this control program and the acreage treated.

(Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(a) et seq.).)

Dated: 22 November, 1977.

EDWIN L. JOHNSON,
Deputy Assistant Administrator
for Pesticide Programs.

(FR Doc. 77-34277 Filed 11-29-77; 8:45 am)

[6560-01]

[FRL 808-5]

**PERSONS EXPOSED TO TRANSURANIUM
ELEMENTS IN THE ENVIRONMENT**

Federal Radiation Protection Guidance on Dose Limits

AGENCY: Environmental Protection Agency.

ACTION: Proposed Federal radiation protection guidance.

SUMMARY: This proposed guidance is addressed to Federal agencies and would contain recommendations intended to assure protection of the public health by limiting the radiation doses persons may receive from transuranium elements present in the environment as a result of existing or possible future unplanned contamination.

The guidance considers both the inhalation and ingestion pathway of transuranium elements to humans and would establish a maximum dose rate to lung and bone for members of the general population. Agencies implementing the guidance would be re-

quired to estimate dose rates to persons from measured air and/or soil concentration levels. Based on available environmental measurements, nearly all the land outside the boundaries of existing contaminated sites is below the levels specified in the guidance and little or no remedial actions would probably be required to achieve compliance.

DATES: Comments must be received on or before February 28, 1977, and should be addressed to: Director, Criteria and Standards Division, Office of Radiation Programs AW-460/CM-2, U.S. Environmental Protection Agency, Washington, D.C. 20460. The Agency will schedule a public hearing if warranted on the basis of comments received.

All written comments filed pursuant to this Notice will be available for inspection and copying in the EPA Public Information Reference Unit, Room 2922, 401 M Street SW., Washington, D.C. during normal business hours.

TECHNICAL DESCRIPTION: A technical summary document explaining the proposed guidance has been prepared by the Office of Radiation Programs. Single copies of this document may be obtained on request from the Director, Criteria and Standards Division at the above address, or from any EPA Regional Office.

**FOR FURTHER INFORMATION
CONTACT:**

Dr. Gordon Burley, Chief, Environmental Standards Branch, Criteria and Standards Division, Office of Radiation Programs (AW-460/CM-2), U.S. Environmental Protection Agency, Washington, D.C. 20460, Telephone Number 703-557-8610.

SUPPLEMENTARY INFORMATION:

Statutory Authority.—Authorities of the former Federal Radiation Council, which was established under Executive Order 10831 and Public Law 86-373, were transferred to the Environmental Protection Agency by Reorganization Plan No. 3 of 1970. It is the Administrator's statutory responsibility (42 U.S.C. 2021(h)) to:

... advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards in the establishment and execution of programs of cooperation with States.

Previous actions by EPA.—This Agency published a Notice of Intent to Review the Need for Establishing New Rules for Plutonium and Other Transuranium Elements in the FEDERAL REGISTER, Vol. 39, page 34098 on September 23, 1974. Public Hearings to gather information were subsequently held in Washington, D.C., on Decem-

ber 10-11, 1974, and in Denver, Colo., on January 10, 1975. The Proceedings of these Hearings were published as EPA Document ORP/CSD-75-1.

Rationale for guidance.—The guidance is intended to provide recommendations on protection of the public health from exposure to transuranium elements at levels above those found in the environment as a result of fallout from the testing of nuclear devices. Accordingly, it proposes to establish a maximum dose rate applicable to the general population which considers all possible important pathways to humans. Two primary criteria used in deriving the proposed guidance were: that any added risk to an individual from exposure to the transuranium elements be very small, and that any actions required by implementation of the guidance be practical. In terms of overall economic requirements, The Agency has found that the costs of remedial actions and benefits of risk reduction differ so greatly between contaminated sites that generic guidance applicable to all sites cannot be provided by formal benefit-cost procedures.

Radiation induced risks can be estimated based on a number of different assumptions, but the most prudent is that there is some finite risk to humans no matter how small the amount of absorbed radiation might be and that the risk at any given low dose level is directly proportional to the damage actually observed at much higher dose levels. The acceptance of such assumptions, in the absence of data to the contrary, must be considered as most appropriate for a regulatory or guidance function. On this basis, there is no level of radiation exposure which is absolutely safe and any radiation dose carries with it some degree of risk. Balanced against this is the fact that in our modern society all persons are exposed to a large number of competing risks (including natural background radiation) and that the reduction of a single risk must be viewed from the overall perspective of the costs and benefits.

The guidance recommendations are intended to achieve adequate health protection for the small fraction of the total population at greatest risk from exposure to transuranium nuclides in the environment, and will therefore offer much greater protection to the vast majority of the population at lesser risk. The risk at the proposed guidance level is estimated to be less than one chance in a million per year and less than ten chances per hundred thousand in a lifetime that an individual would develop a cancer from continuous exposure at the stated dose rates. It must be recognized that these estimates are not precise, and have an uncertainty of at least a factor of three for cancer risk.

There may be differences in reputable scientific opinions on their accuracy, but they represent the best judgment of the Agency. The social judgment of whether this risk level is acceptable will be subject to public comment during the period provided. The final Agency recommendation may be higher or lower as appropriate.

Other Federal regulatory actions have considered lifetime risk levels for other carcinogens but there is, at this time, no uniformity of approach to the regulations of carcinogens. The lifetime risk levels proposed range from one per million as "virtually safe" to greater than 300 per million. Differences in the action levels reflect different regulatory requirements, constraints associated with remedial actions for a particular carcinogen, uncertainties in the calculations, differences in methods used to derive lifetime risks, and economic considerations.

The Agency has recognized a difference between those sites presently contaminated and sites that may be accidentally contaminated in the future, and has considered whether separate numerical guides should be developed for these two cases. It was concluded that no specific rationale is known that would justify different guidance based on health risk considerations. Therefore, the Agency recommends that the same numerical guide be used in both cases, but that all future contamination be cleaned up as soon as possible after occurrence in order to minimize radiation exposures of the general public and prevent widespread dispersion of environmental contamination.

The Agency has also considered the costs which might be involved in implementing this guidance, based on the information available. These costs were estimated from soil contamination levels at existing sites of contamination. A reference level of soil contamination was chosen which, with a very high degree of probability would be expected to result in an inhalation dose to an individual not to exceed the guidance recommendation. The costs of implementing the guidance can be expected to vary by location, contamination level, and other factors. A minimum cost of \$500 per acre has been assumed for estimating the total costs which may be incurred in bringing all areas above the designated level into compliance. Such costs include dilution or removal of contamination by plowing or scraping as required and restorative actions needed to prevent erosion and assist ecological recovery. Costs necessarily increase as the difference between the existing contamination levels and those sought becomes greater. Results are discussed below in more detail. It can be concluded that the costs of implementing

the guidance at the reference level would be reasonable and achievable, but that the cumulative costs increase rapidly when lower guidance limits are considered.

On the basis of the above considerations, the Agency has concluded that the proposed guidance would provide adequate protection of the critical segment of the population and would be capable of implementation at reasonable cost. Further details are provided in the technical summary document, which is available on request.

Scope of guidance.—The proposed guidance is not intended to supersede existing radiation protection guides, such as the individual and population limits established by the Federal Radiation Council in 1960, but rather to supplement these by specifying limits for one type of source and for one group of radionuclides within these broader limits. The scope of the proposed guidance includes all transuranium element contamination in the general environment from all sources. The recommendations are applicable to individuals in the general population outside the boundaries of a Federal facility, Federally licensed facility, or other site under the direct control of a Federal agency. The limits apply specifically to the critical segment of the exposed population, which is that group of persons in the general population who, because of residency or other factors, can on the average be expected to receive the highest lifetime radiation dose from a specified source of transuranium elements.

The recommendations are given in terms of an annual limiting dose commitment to the pulmonary region of the lung or to bone. Although the proposed guidance specifies dose rate limits to only these organs, this also limits the potential accumulation in other body organs including gonadal tissues. The annual dose rate to the designated organs can be estimated from representative measurements of air concentrations or soil contamination levels, either by use of site-specific data or by use of calculations based on reasonable procedures and assumptions.

Risk perspectives.—It is known that exposure to radiation may increase somatic risks, primarily that of cancer, as well as genetic risks to future generations. The proposed guidance is based on suitable models chosen by the Agency that relate environmental levels to the dose to internal organs. Health risks resulting from radiation exposure were estimated using models and recommendations of the Advisory Committee on the Biological Effects of Ionizing Radiation of the National Academy of Sciences (NAS-BEIR Committee) in its reports entitled "The Effects on Populations of Exposure to Low Levels of Ionizing Radi-

ation" (1972), and "Health Effects of the Alpha-Emitting Particles in the Respiratory Tract" (1976) as well as information in other technical reports.

The radiation risk due to inhalation of transuranium elements is primarily lung cancer. Additional risks may result from translocation of a small fraction of the transuranium elements from the lung to other body organs, especially to the liver and bone. On the basis of models, it was estimated that, for a cohort of 100,000 persons followed through their entire lifetimes, the continuous inhalation over their lifetimes of transuranium aerosols leadings to an average annual dose rate to the pulmonary tissue of 1 mrad/year per person could potentially result in 10 premature cancer deaths. For an Average lifespan of 71 years, the annual risk to each person from lifetime exposure at this level is about one per million per year.

The radiation risk due to ingestion of transuranium elements is primarily bone and liver cancers. In a cohort of 100,000 persons, continuous ingestion over a lifetime of a transuranium radionuclide at a level causing an average skeletal (bone) dose rate of 3 mrad per year 70 years after the start of ingestion could potentially result in less than 6 premature deaths from such cancers.

Genetic damage is possible as a result of assimilation of transuranium elements in gonadal tissue. There is considerable uncertainty in the estimated dose to gonadal tissue and resultant genetic risk but it can be estimated that, for continuous ingestion at the limits set by this proposed guidance, the total dose to gonadal tissue over 30 years of chronic exposure would be about 10 millirad. Such a gonadal dose to each of the parents is estimated to produce 1 to 20 genetic defects per 100,000 live births in the first generation. This number can be compared to the approximately 6000 genetic defects normally observed in 100,000 live births.

In practice, very few, if any, individuals are expected to be subjected to the recommended guidance limits and the total number of individuals exposed above levels of worldwide fallout will be small. The Agency also considered the total impact on population groups but, because the exposed population groups are small and are likely to remain so, it was deemed unnecessary to separately consider the total population radiation dose commitment in developing this guidance.

Implementation.—Implementation of this guidance would require measurement of the ambient concentration level of transuranium elements in air, soil, food, or water, and conversion through models to dose estimates. In most cases the critical pathway for exposure to transuranium elements is

through inhalation of airborne particulates derived from resuspension of soil particles and compliance with this dose guidance can be demonstrated by measurements of air and/or soil concentration. Air concentration may be related to the dose guidance using dosimetry models that include consideration of particle size distribution and other parameters appropriate to the specific site of contamination. Soil contamination levels can be related to a corresponding air concentration by use of a resuspension factor, which is obtained either by experimental determination or by calculational techniques.

For practical reasons of facilitating implementation of the proposed guidance, derived numerical values for level of soil or air concentrations, which can reasonably be predicted to result in dose rates less than the guidance recommendations, could be substituted for the site-specific values. On the basis of limited data available for several existing sites, the Agency suggests that a soil contamination level of $0.2 \mu\text{Ci}/\text{m}^2$, for samples collected at the surface to a depth of 1 cm and for particle sizes under 2 mm, would establish a reasonable "screening level" for this purpose. The Agency also suggests that a derived air concentration based on an activity median aerodynamic particle diameter (AMAD) not to exceed $0.1 \mu\text{m}$, which is substantially smaller than observed values at all known contamination sites, could be equated to a limiting concentration of about $1 \text{ fCi}/\text{m}^3$ for alpha emitting transuranium nuclides. Use of such derived numerical values can serve to reduce the land areas requiring evaluation and minimize the number of measurements needed. Areas which do not exceed the "screening level" would generally be considered in compliance with the guidance recommendations; those that exceed it would require more intensive evaluation to determine actual dose rates to exposed persons.

Remedial actions and economic evaluation.—Where a need for the use of remedial measures would arise, two alternatives are available: (1) reduction or elimination of the source term; or (2) establishing restricted access or use of the area in question. Remedial measures which reduce or remove existing surface contamination, in order to minimize the source term and subsequent transport of plutonium to humans, include:

1. In-place stabilization by the application of a relatively impermeable cover, such as oil, polymerized plastics, or asphalt;
2. Dilution by plowing or other similar techniques; and
3. Disposal by removal of surface soils and burial either on-site or in a designated waste storage repository.

It can generally be expected that a variety of techniques could be used to

achieve the guidance level at any site. An economic evaluation can be used to identify the technique or combination of techniques that will attain and maintain the guidance level at the least total cost. Monetary costs, environmental costs, and other nonmonetary costs should all be considered in the evaluation of each alternative combination of possible remedial actions.

Projected impact of guidance and alternatives.—Under the provisions of the National Environmental Policy Act of 1969, it is required that every major Federal action be examined in terms of projected impacts and that all available alternatives be considered. The purpose of such an analysis is to compare the costs and benefits of the recommended action with other options in terms of the broad range of projected health, sociological, economic, and environmental impacts.

The implementation of the proposed action would be site-specific. The portion of the environment affected is that where present or future transuranium nuclide concentrations may exceed guidance values. Such areas are likely to be those where the transuranium elements are prepared, fabricated, used, stored, or transported. A number of such areas currently exist within the limits of the continental United States. Most contamination is located on lands with restricted or limited access, but a few instances exist where contamination has spread to privately owned properties.

There are four Federal sites in the United States that have transuranium element contamination above ambient levels in soils beyond their boundaries. These include the Rocky Flats Plant in Jefferson County, Colo., Mound Laboratory in Miamisburg, Ohio, Nevada Test Site in southern Nevada, and Trinity Test Site near Alamogordo, N. Mex. The majority of all contamination released is confined within areas under the direct control of the Federal government, which imposes restrictions on the access and use of these areas. Relatively small amounts of transuranium element contamination exists outside the boundaries of these sites on lands generally accessible to the public.

The following discussion is intended to supply a perspective of applying the guidance recommendations to these sites in terms of the reference level of $0.2 \mu\text{Ci}/\text{m}^2$, and is based on all the information presently available to the Agency. Use of such a reference level for soil contamination is intended solely to provide a basis for comparison and in most cases probably overestimates the magnitude of the areas subject to remedial actions. Comparisons are made in terms of areas outside the boundaries of these sites which may exceed the derived soil reference level.

The Rocky Flats Plant (RFP) produces components for nuclear weapons. Barrels containing plutonium contaminated cutting oil slowly corroded and some of the contents eventually leaked into the environment and were dispersed. On the basis of soil concentration data, all offsite areas at the Rocky Flats plant probably would be in compliance with guidance recommendations. However, more intensive evaluation in the most highly contaminated areas east of the plant may be needed to determine the actual dose rates to the general population. The area is sparsely inhabited and there are few people living in the particular area of concern. All local water supplies are expected to yield ingestion dose rates well below the guidance recommendations.

Mound Laboratory is a major research and development site for fabrication of radioisotopic heat sources used for space and terrestrial applications. In 1969 a pipeline transporting a waste Pu-238 solution ruptured, spilling the contaminated solution. The plutonium migrated slowly into nearby waterways. The majority of the plutonium is now sorbed and fixed on the sediments of the North and South Canals. Maximum concentrations are 1 to 3 ft. below the sediment surface and currently do not pose any radiation problem, since very little of the plutonium is in soluble form and the canal water is not used for drinking purposes. Banks immediately adjacent to the canal and overflow creek, which are subject to occasional flooding, have maximum plutonium concentrations exceeding the reference level. The amount of land in question is about 0.01 mi² and there are no people living on this land. No immediate cleanup is indicated for this site, but continued surveillance is warranted.

The Nevada Test Site (NTS) covers an area of 1400 mi² with an additional exclusion zone extending distances of 16 to 48 miles. Major programs at NTS have included nuclear weapons tests, testing for peaceful uses of nuclear explosives, and nuclear reactor engine development. These activities have resulted in plutonium contamination in certain areas of the test site and exclusion areas and slight contamination (above worldwide fallout levels) outside the exclusion areas. There are no known uncontrolled areas which have transuranium element contamination exceeding the reference level.

The Trinity Test Site was the location of the first nuclear explosion. No other nuclear explosion tests were performed at Trinity. A site survey was performed by EPA during 1973-74 to determine residual plutonium concentration contours. The highest plutonium contamination levels in uncontrolled areas ranged from .02 to .09 $\mu\text{Ci}/\text{m}^2$. On the basis of limited avail-

able data, no major remedial actions would appear to be necessary at this site.

Text of proposed guidance.—The Environmental Protection Agency proposes that the following recommendations be submitted by the Administrator to the President for issuance as Federal Radiation Guidance:

1. The annual alpha radiation dose rate to members of the critical segment of the exposed population as the result of exposure to transuranium elements in the general environment should not exceed either:

- a. 1 millirad per year to the pulmonary lung, or and
- b. 3 millirad per year to the bone.

2. For newly contaminated areas, control measures should be taken to minimize both residual levels and radiation exposures of the general public. The control measures are expected to result in levels well below those specified in paragraph one. Compliance with the guidance recommendations should be achieved within a reasonable period of time.

3. The recommendations are to be used only for guidance on possible remedial actions for the protection of the public health in instances of presently existing contamination or of possible future unplanned releases of transuranium elements. They are not to be used by Federal agencies as limits for planned releases of transuranium elements into the general environment.

Definitions.—a. "Critical segment of the exposed population" means that group of persons within the exposed population receiving the highest radiation dose to the pulmonary region of the lung or to the bone.

b. "Rad" is the unit of absorbed dose, defined as the energy imparted to tissue due to ionizing radiation divided by the mass of the tissue. One rad is equal to the absorption of 100 ergs of radiation energy per gram of matter. 1 millirad (mrad) = 10^{-3} rad.

c. "Pulmonary lung" means that region of the lung consisting of respiratory bronchioles, alveolar ducts, atria, alveoli, and alveolar sacs. The average total weight of this tissue, including the capillary blood, is assumed to be 570 gms.

d. "Millirad per year to the pulmonary lung" means the equilibrium dose rate following chronic inhalation. This dose rate is calculated by dividing the alpha energy absorbed per year in the pulmonary lung by its mass.

e. "Bone" means osseous tissue. The average total weight of this tissue is assumed to be 5000 grams.

f. "Millirad per year to the bone" means the dose rate attained after 70 years of chronic exposure. This dose rate is calculated by dividing the alpha energy absorbed in the bone during the 70th year by the bone mass.

g. "General environment" means the total terrestrial, atmospheric and aquatic environments outside the boundaries of Federally licensed facilities or outside the boundaries of sites which are under the direct control of a Federal agency.

h. "Curie (Ci)" is the basic unit to describe the intensity of radioactivity in a material. It is equal to 37 billion disintegrations per second.

1 millicurie (mCi) = 10^{-3} Ci

1 femtocurie (fCi) = 10^{-15} Ci

Dated: November 22, 1977.

DOUGLAS M. COSTLE,
Administrator.

[FR Doc. 77-34328 Filed 11-29-77; 8:45 am]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

RADIO ASTRONOMY SERVICE WORKING GROUP AND BROADCAST SATELLITE SERVICE WORKING GROUP FOR THE 1979 ITU WORLD ADMINISTRATIVE RADIO CONFERENCE

Joint Meeting

NOVEMBER 23, 1977.

A joint meeting of the Radio Astronomy Service Working Group and the Broadcast Satellite Service Working Group for the 1979 General World Administrative Radio Conference is scheduled to be held on Thursday, December 15, 1977, at 1 p.m. in room 8210 of the Commission's offices located at 2025 M Street NW., Washington, D.C.

This joint meeting will be held to discuss mutual problems and possibilities of shared allocations in the 2670 to 2700 MHz band.

The joint advisory committee meeting is open to the general public and any written comments will be accepted before or after the meeting.

For the Federal Communications Commission.

WILLIAM J. TRICARICO,
Acting Secretary.

[FR Doc. 77-34282 Filed 11-29-77; 8:45 am]

[6712-01]

SATELLITE BROADCASTING SERVICE GROUP
1979 WORLD ADMINISTRATIVE RADIO CONFERENCE

Schedule of Meeting

NOVEMBER 25, 1977.

Pursuant to Pub. L. 92-463, notice is hereby given of the following meeting.

WARC-79 SATELLITE BROADCASTING SERVICE GROUP

Thursday, December 15, 1977, 9:30 a.m. to 12 Noon, Room 8210, 2025 M Street NW., Washington, D.C.

FOOD CHEMICAL NEWS

Editor: Louis Rothschild, Jr.

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Assistant to the Editor: Natalie Pargas

Assistant Editor: Patricia Mitchell

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PVC ORDER, UNDER ACRYLONITRILE DOCTRINE, BEING DRAFTED

Food and Drugs Commissioner Donald Kennedy held out little hope for continued use of polyvinyl chloride food packaging materials in a Nov. 8 letter to Ethyl's Dr. C. M. Neher.

Kennedy said the final rule "will necessarily reflect many of the judgments and conclusions of law reached in the related final decision on the status of acrylonitrile ..." (See FOOD CHEMICAL NEWS, Sept. 26, Pages 47, 50 and 53).

In the acrylonitrile matter, FDA held that if any migration of a carcinogenic indirect additive into any food under any circumstances has been shown, there is a reasonable expectation of migration of the substance into food.

FDA has proposed banning use of PVC in rigid, semi-rigid packaging (See FOOD CHEMICAL NEWS, Sept. 1, 1975, Page 34), but the proposal would retain use in films, coatings, and cap linings. It is these uses that appear to be in jeopardy because of the acrylonitrile ruling. The FDA proposal included an interim Food Additive Order for use of PVC in water pipes.

Since the 1975 proposal, Kennedy wrote, "toxicological studies have established vinyl chloride as a carcinogen in both animals and man."

Sending Neher a copy of "a new and as yet unpublished FDA analytical procedure for vinyl chloride detection," Kennedy said:

"However, we intend to proceed as expeditiously as possible with the publication of a final rule of polyvinyl chloride copolymers. Any and all relevant scientific data made available before publication will be objectively considered in formulating our final decision."

The Commissioner noted that Ethyl requested "additional time to rework your study in order to obtain convincing data which may demonstrate that the vinyl chloride monomer in your applications is not reasonably expected to migrate to food." Discussing a September 8 meeting of Neher with staffers of FDA's Bureau of Foods, Kennedy wrote:

"I am aware that over the past ten months the Ethyl Corporation has submitted data to demonstrate decreasing migration of vinyl chloride from production samples of your polyvinyl chloride copolymers. As noted in the Sept. 8 meeting, our staff discovered that due to various

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deficiencies in the sensitivity and reliability of your data, they were unable to confirm at what level deviation from the linear diffusion model actually occurs.

"Our chemistry staff has attributed part of the problem to your imprecise determination of residual vinyl chloride in the copolymer itself. Of course, this uncertainty makes difficult a reliable correlation between residual monomer and any migration that may be measured."

Applying the acrylonitrile doctrine to the PVC issue, Kennedy said:

"The conclusions of the acrylonitrile document concerning migration of monomer resulted from my concurrence with the decision that the linear diffusion process was confirmed by experimental data at a temperature, concentration, and storage time 'reasonably close to the values associated with normal use,' and that extrapolation of this behavior to regions below which no measurement of monomer could be made is justified.

"As stated in the document, we grant the possibility that there could be deviations from the linear diffusion model in extreme conditions, and thus 'The reasonable expectation of migration, arrived at on the basis of the diffusion principle, is not unalterable ... The expectation can be rebutted, but only if an adequate showing is made that migration is not reasonably to be expected.' This is obviously what you hope to accomplish in your proposed experiments.

"A mere deviation from the linear diffusion model, however, would not be sufficient to satisfy this standard. Rather the deviation must be such as to show that migration of vinyl chloride cannot reasonably be expected. Such a finding cannot be made if data are imprecise."

The FDA acrylonitrile decision is being appealed in court by the Society of the Plastics Industry, Monsanto, Vistron, and The Continental Group (See FOOD CHEMICAL NEWS, Nov. 21, Page 41; and Nov. 28, Page 2).

It is anticipated that other firms in the food packaging industry -- and perhaps also in the food industry -- will file amicus curiae briefs in the case because of the broad implications of the acrylonitrile doctrine to all food-packaging materials.

The filings of legal papers in the acrylonitrile case starts with FDA filing of a certified index of the record within 40 days of the petition for appeal, which will be followed by briefs. It is estimated that the case may not go to oral argument before next summer, and that a final decision may not come until fall of 1978.