

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).

#### 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).

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 from 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.

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

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"(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 tumors. 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.

#### 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