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ETHYLENE DIBROMIDE: REGULATORY BACKGROUND

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SUMMARY

On February 3, 1984, EPA announced the emergency suspension of EDB use as a fumigant for raw grain and milling machinery. This action was issued in light of additional data concerning EDB residues in grain-based consumer products.

In September 1983 EPA had issued a regulatory decision only suspending EDB use as a soil fumigant immediately, and proposing to phase out most of its remaining uses over the next 12-18 months. In September EPA cited significant new evidence that EDB is contaminating groundwater supplies in a number of States, and promised to further investigate possible EDB residues in food.

Registration to use EDB to fumigate citrus was cancelled in the September 1983 decision, effective in September 1984. Residues in treated fruit have also been a subject of public concern; EPA reexamined this issue and in March 1984 announced interim residue tolerance levels, and set a permanent zero-level tolerance effective in September 1984.

Laboratory test results have shown EDB to be a potent carcinogen and mutagen, and a cause of reproductive disorders, in test animals.

Between September 1983 and February 1984, a number of States began to test for the presence of EDB in consumer food products. Upon discovery of EDB residues, the State of Florida stopped the sale of specific lots of these

products, and other States considered similar measures. EPA had never established an allowable residue tolerance for EDB in these foods, which left the States little guidance as to what constitutes a safe or unsafe level of EDB.

In the February 1984 announcement, EPA recommended maximum permissible residue levels of 900 ppb (parts per billion) on raw grain products, 150 ppb on grain products requiring further processing (such as a cake mix), and 30 ppb on ready-to-eat products (such as bread or cookies). It is still unclear the extent to which EDB has been used to treat cereal grains. Estimates of the amount of raw grain treated with EDB range from 2-50%.

The March 1984 announcement established an interim tolerance of 250 ppb on citrus. This is a whole fruit tolerance which is equivalent to a 30 ppb level in the edible portions. After September 1, 1984, no levels of EDB residue will be allowed on domestic or imported citrus and papaya.

WHAT IS EDB?

EDB, a persistent halogenated hydrocarbon, has been registered as a pesticide since 1948. Over 300 million pounds of EDB are produced annually in this country. Over 20 million pounds are used as a pesticide. The remainder is used as an additive in leaded gasoline.

Of the 20 million pounds of EDB used for agricultural purposes, over 90 percent is used as a soil fumigant. The use of EDB as a soil fumigant was suspended in September 1983. The remaining uses of EDB were to fumigate stored grain and grain milling machinery, as a fumigant to quarantine citrus and other tropical fruits, and for a number of minor uses. Subsequent decisions have ended virtually all EDB use by the present time.

EPA's DECISIONS*

EPA's authority to regulate pesticides is given by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires that a pesticide be registered with EPA before it can be used. This registration is based upon a review of health and safety data, and is to guarantee that the product can be used without unreasonable adverse effects. If later information indicates unreasonable adverse effects, EPA can move to suspend or cancel the pesticide's registration.

The September 1983 emergency suspension (the most restrictive measure EPA can take under the law) immediately stopped the sale and distribution of EDB for soil fumigation. In this use it was applied prior to planting to control nematodes and other soil insects. As a soil fumigant it was used on citrus and fruit trees, soybeans, pineapples, cotton, tobacco, peanuts, and over 30 additional fruit and vegetable crops. Most of these uses are concentrated in the southern states, California, and Hawaii where the soil pests are the greatest problem. Tests have found the chemical in groundwater in California, Florida, Hawaii, and Georgia.

In February 1984 EPA announced an emergency suspension of EDB for fumigation of stored grain and grain milling machinery. The suspension order legally halts the sale, distribution and actual use of EDB products for these purposes. EPA also recommended maximum acceptable levels of EDB residues in three categories of grain-based foods: raw grain intended for human consumption (900 ppb); consumer products requiring further preparation

*For the convenience of the reader, a chronology of events is given at the end of this paper.

(150 ppb); and ready-to-eat products (30 ppb). EPA also initiated actions to remove impediments to Federal enforcement of the recommended levels. These actions include revoking the existing exemption from tolerance requirements for residues of EDB resulting from grain fumigation, and revoking tolerances for inorganic bromide resulting from EDB fumigation of grain and other commodities.

The September 1983 EPA cancellation order also ordered a phase out, by September 1, 1984, of the use of EDB for quarantine fumigation of citrus fruits, tropical fruits such as mangos and papaya, and other fruits and vegetables which can be the host for tropical fruit flies. The interim period was allowed to provide time for further development and implementation of alternatives. On March 2, 1984, EPA announced interim tolerance levels of 250 ppb for citrus and papaya, and allowed use to continue until September 1. After that date, these will be a zero tolerance for these fruits, and no further EDB use will be allowed. Gamma irradiation and cold storage treatments are alternatives currently under consideration (see CRS white paper: "Preservation of Food by Irradiation" by Donna Porter, June 21, 1983). Much of the fumigated fruit is shipped to Japan, which requires some kind of quarantine treatment.

Some very minor uses of EDB will be allowed to continue, though label changes will be required. These include the fumigation of stored beehives and hive platforms to control wax moths; use on vault-stored clothing and furniture; and the U.S. Department of Agriculture's Japanese Beetle Program.

These actions are part of EPA's investigation of EDB under the procedure called Rebuttable Presumption Against Registration (RPAR). This formal process is started when the Agency has evidence that a pesticide may cause unreasonable adverse effects in humans or the environment. In 1975, the National Cancer Institute issued a notice that EDB appeared to induce cancer in laboratory animals. In 1977, following evidence that EDB also posed additional risks, EPA began the RPAR review. In December 1980, after further research on the use of EDB, and after analyzing the public comments concerning risks and benefits, the Agency issued a proposed decision to cancel the pesticide for fumigation of stored grain, milling machinery and felled logs, and to phase out the use of EDB for citrus and vegetable quarantine fumigation over a period of two years. In this 1980 proposal, use of EDB for soil fumigation was to be retained since this use did not appear to result in significant human exposure. Between 1980-83, discovery of groundwater contamination by EDB caused EPA to propose an end to this use as well.

FIFRA allows manufacturers and registrants of EDB products to appeal EPA's decisions. None of the suspended uses has been appealed. The cancellation order for felled log fumigation, which accounts for a small amount of EDB use, has been appealed by the state of Colorado. Appealing a cancellation order initiates hearings which review the risks and benefits of the pesticide products. Uses of the pesticide are allowed during the cancellation hearings. These hearings usually take one or two years to complete.

The use of EDB in gasoline was not considered as part of these decisions. Used in gasoline, EDB keeps lead from collecting on an engine's cylinder walls. Concentrations in gasoline are less than 0.5 percent. According to EPA's September 1983 press release, preliminary analysis of exposure to EDB from gasoline vapors shows that these exposures are much lower than those resulting from agricultural uses. However, some observers believe that ambient EDB levels from gasoline use are not trivial. The State of New York estimated higher EDB risks than EPA did, based in part on an assessment of these estimated ambient exposures.

EDB Residues in Food

As part of a registration decision, EPA decides what amount of a pesticide will present no unreasonable risk to the eventual consumers of the treated crop. These are "pesticide residues" which are granted a "tolerance" from EPA. This is the amount EPA calculates as safe assuming a lifetime of exposure via the foodstuff. EPA grants the tolerance, but it is enforced by the Food and Drug Administration.

In 1956, EDB grain fumigation uses were granted an exemption from tolerance requirements, because it was believed that the pesticide dissipated during the processing of the food. Modern detection technology now shows this assumption to be incorrect. EDB tolerances on citrus were not exempted in 1956 or any later time; an interim tolerance was granted in March 1984.

EPA has known that EDB does not entirely dissipate for some years. Their 1980 EDB regulatory support document discusses 1978 studies showing

the presence of EDB in flour and baked goods. According to EPA's 1983 support document, the 1980 document somewhat underestimated the residues of EDB in stored grain. In the 1983 document, EPA stated that the risk estimates from bulk grain fumigation were found to present the major known dietary risk from EDB. The 1983 report found EDB levels in 20 of 22 flour samples; the levels ranged from none detected to 4200 ppb (parts per billion). In the 20 samples found with EDB, residue levels in biscuits baked from the flour detected with EDB ranged from none detectable to 260 ppb, and averaged 36 ppb.

In hearings before the House Government Operations Committee on March 5 and 6, 1984, it was reported that there was some knowledge of EDB residues in food as early as 1965.

During this time EPA did not issue a tolerance for EDB residues on cereal grains or citrus, nor were the registrants required to submit an application.

Coordination Between EPA and FDA

Allowable residue levels are determined by EPA but are enforced by the Food and Drug Administration (FDA). For raw agricultural commodities, such as unprocessed grain or citrus, the tolerance is enforced under authority of FIFRA. For processed foods, such as wheat flour, the tolerance is enforced under authority of the Food, Drug and Cosmetic Act (FDCA). This is because a pesticide residue is considered a "food additive" after the raw commodity has been processed. Section 409 of the FDCA includes the Delaney Amendment, which does not permit food additives which have been established as animal

carcinogens. However, Section 402 of the FDCA states that a foodstuff cannot be considered adulterated if the residue level in the processed food is the same or less than the level allowed on the raw agricultural commodity.

As a result of EDB levels declining during processing (due to aeration, baking, etc.), the Delaney Amendment is interpreted not to apply. However, once EPA sets a tolerance for the raw agricultural commodity, this also determines, to an extent, the ceiling of allowable residues in processed foods. A relatively high tolerance for the raw commodity might prevent actions against processed foods at levels above EPA's recommendations. Setting a low residue level aimed at the retail consumer level could leave much stored grain to be considered "adulterated".

To avoid these dilemmas, EPA relies on "action levels" to be used by FDA. These levels are Federally enforceable as evidence that "good manufacturing practices" have been followed. Such decisions are administrative ones issued by FDA with relatively little procedural requirements. Many States require FDA action levels to be binding. Residues found to be above the FDA action levels would trigger FDA investigation as to whether or not good manufacturing practices were followed. However, establishing action levels instead of residue tolerances does raise some questions of uniform enforcement of these standards. Also, some environmental groups have threatened litigation should EPA not only revoke the 1956 exemption from tolerances requirements, but also establish a zero tolerance for finished food products which are ready for human consumption.

Quarantine Fumigation

EPA's September 1983 decision on EDB as a quarantine treatment for citrus and tropical fruits was to cancel this registered use effective September 1, 1984. EPA explained that this phase-out period was needed to clarify both the availability and acceptability of alternative quarantine treatments. EPA felt that more information was needed about residues, alternatives, and international trade. In March 1984, EPA announced an interim residue tolerance level of 250 ppb on the whole fruit, and as of September 1, 1984, no EDB residues will be allowed on citrus and papaya.

The extent of fumigation varies.* For example, EPA estimates that Texas fumigates approximately 20 percent of its exported citrus, while California requires all citrus imported from Florida to be fumigated (however, California recently decided to deny entry to EDB-treated fruit). Estimates of the amount of exported California citrus which is fumigated include: 17 percent of the oranges, 35 percent of grapefruit, and 44 percent of other fresh citrus.

It is estimated the economic benefits* of EDB to the citrus industry are some $30 million in trade that could be lost if the pesticide is banned. Some $24.7 million of this consists of grapefruit exports to Japan.

For the average U.S. consumer of citrus and tropical fruits, the most likely source of EDB exposure is from imported products.

Quarantine requirements for citrus and tropical fruits prevent the spread of potentially devastating infestations of several species of fruit

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*These estimates are given in EPA's "Ethylene Dibromide: Position Document 4", September 1983.

flies. The U.S. requires most fresh citrus and tropical fruits shipped into the mainland U.S. to be fumigated with EDB. Some fruits shipped within the U.S. to Texas, New Mexico, Arizona, and California must also be fumigated. Thus, decisions on EDB potentially affect: (a) imports from Latin American, Caribbean and Mediterranean nations; (b) exports to Japan; and (c) some fruits shipped in interstate commerce.

EPA estimates that only a small percentage of all citrus consumed in this country is treated with EDB. Of the 5.8 billion pounds of citrus consumed, about 40 million pounds is imported fresh fruit (most is fumigated), and about 55 million pounds is fumigated for domestic interstate quarantine. This is about 2% of the total consumed. Citrus intended for processing into juice is not fumigated.

According to EPA, residents of the Southwest, with increased portions of EDB-treated citrus in their diets, were assumed to have been exposed to greater amounts of EDB. Average EDB residue levels in edible portions of citrus, collected by EPA from Sunbelt supermarkets, have ranged from a 51 ppb level in grapefruit to a 48 ppb level in oranges. Recently, California officials have reported Florida citrus pulp to contain an average of 200 ppb over the last five years. EPA estimates the increased cancer risk over a lifetime of eating treated citrus is 1 in 100,000 from EDB for the average consumer.

Alternatives to ethylene dibromide include the use of other chemicals such as methyl bromide. Gamma irradiation of citrus, along with cold storage of the fruit, are also new techniques under development. The FDA

is currently looking at the method of irradiating fruit and vegetables as an alternative to quarantine fumigation, though any new method must be approved both by the U.S. Department of Agriculture and the importing States. Some of the alternative, non-pesticide control methods (e.g, cold storage treatment) already have been approved by FDA but await greater industry and consumer acceptance. Until EDB-use is banned or an effective alternative product or method is marketed, EDB will remain as a major quarantine fumigant of choice of many exporting and importing countries.

OCCUPATIONAL EXPOSURE

On October 7, 1983 the Occupational Safety and Health Administration (OSHA) proposed a stringent revision (48 CFR 45956) in the present standard regulating employee exposure to EDB. The proposal would reduce the present limit of 20 ppm (parts per million) of air to .1 ppm (to compare to the food levels discussed earlier, 20 ppm is equivalent to 20,000 ppb and .1 ppm is equal to 100 ppb). The proposal would also add requirements for exposure monitoring, employee education, and the like. OSHA estimates that 56,000 workers are exposed to EDB for varying periods; others have estimated the number of exposed workers at 100,000 (these estimates include grain use exposures which have now been suspended).

In testimony at congressional hearings (Sept. 13, 1983 hearings before the House Education and Labor Subcommittee on Labor Standards), labor groups have expressed dissatisfaction with the OSHA proposal. They believe the proposed monitoring and training requirements to be inadequate. Of special concern is that the proposal exempts employers that expose their employees to EDB

for less than 30 days per year from requirements to install feasible engineering controls (such as ventilation fans) or adopt work practice controls (such as providing more time between fumigation and worker re-entry). Labor officials view this exemption as too broad and unnecessary. It could exempt many workers exposed to EDB. Furthermore, these simple enginering controls and revised work practices have been required for over two years in the State of California with reportedly little negative impact on employers. Instead of these control measures, OSHA's proposal would require personal protective devices (respirators) to be used by workers. The unions maintain that respiratory protection is often ineffective, cannot be used by everyone, and provides no protection against skin absorption.

The other major complaint is that the exposure levels will not be immediately reduced.

In light of the health risks of EDB, the unions have repeatedly petitioned OSHA to issue an emergency temporary standard to reduce exposure immediately. OSHA has denied these petitions explaining that there is no documented evidence of an emergency, although such measures have been recommended to OSHA by the National Institute of Occupational Safety and Health (NIOSH).

The current standard of 20 ppm is within the range of exposure which induced tumors in the National Cancer Institute animal inhalation studies. Some studies showed tumor-causing effects to occur at 10 ppm, with a strong does-response relationship up to the 40 ppm level. Finding a carcinogenic effect in laboratory animals at levels within the permissible occupational

exposure is unusual. This finding of adverse effects at relatively low levels is partially behind the NIOSH recommendation for an emergency standard to immediately reduce allowable exposure levels.

EPA, under FIFRA, has no authority concerning occupational exposure standards to EDB. However, as EPA has suspended almost all uses of EDB, this makes the OSHA rule relatively moot. The highest exposure groups are those who work in agriculture-related situations--grain mills, food warehouses, and the like. The EPA actions on citrus and grain fumigation uses effectively stop most of the exposure to such high risk groups. As a result, labor union representatives have taken an interest in not only the rulemaking activity of OSHA, but also that of EPA.

Related Issues

Some of the confusion about appropriate responses in light of EDB residues has been resolved by EPA's guidelines. Nevertheless, at least two issues remain:

1) how safe are levels of EDB which are below the suggested tolerance; and

2) is this situation unique, or will it be repeated in the future with other pesticides?

The first question, "How safe is safe," has no obvious answer. Many observers compare EDB risks to other widespread, potential cancer-causing trace contaminants. For example, aflatoxin, a very potent animal carcinogen (more potent than EDB), is a naturally-occurring substance in many foods (especially grain), and has an allowable residue level of 20 parts per billion in food. This level of allowable aflatoxin may add some perspective to proposed EDB tolerance levels. However, overall Federal regulatory

policy has been that avoidable exposures to animal carcinogens should be minimized. As a result, tolerance levels are likely to remain controversial until EDB residues in the food supply approach zero (estimated to take 3-5 years).

The second issue is more general and concerns the overall residue level-setting process. There are a variety of pesticides whose residue tolerances were developed and granted without the benefits of modern detection methods or of what are now considered essential chronic health data. GAO and Congress have issued numerous reports in the last 5-10 years strongly criticizing EPA's tolerance-setting procedures and program. The Agency's program has been continually upgraded in light of these reports and recommendations from other sources. However, it is likely that other pesticides which have been in widespread use for many years will raise similar policy issues in the future--how timely has EPA been in its review of these older products, and, should allowable residue levels be revised in light of new data? The recent "discovery" of EDB and its lack of established tolerances may bring these issues more directly into the FIFRA reauthorization debate during the second session of the 98th Congress.

Other older pesticides which are possible alternatives to EDB may also be hazardous. There is less data available about some of these other pesticides, and it will take years before all have been fully characterized with complete registration data. Methyl bromide has been reported in the Washington Post as being positive in a recent animal cancer test. Carbon tetrachloride has been under EPA's RPAR review since 1980. For more information about health effects of EDB and its alternatives, see CRS white paper: "Ethylene Dibromide", January 26, 1984, by Michael Simpson.

EDB CHRONOLOGY*

1927: Studies first document EDB's toxicity to animals.

1948: Ethylene dibromide introduced as a pesticide.

1954: Congress amends the Federal Food, Drug, Cosmetic Act, mandating the setting of safe tolerance levels for pesticides in foods.

1956: FDA ruling exempts bromide fumigants such as EDB from regulation regarding pesticide residue standards. This was based on the belief that the pesticides would be dissipated in the processing of food.

1958: Delaney Amendment to the Food, Drug and Cosmetic Act banning the use of any carcinogen (cancer-causing agent) as a food additive.

1970: Environmenal Protection Agency established.

1971: OSHA issues a 20 ppm standard for EDB as a maximum safe exposure level for workers over an 8 hour day.

1974: National Cancer Institute (NCI), in a "Memo of Alert", warns that EDB is a potent carcinogen.

1975: Final NCI report on cancer hazard of EDB.

1975: Environmental Defense Fund petitions EPA to initiate Rebutable Presumption Against Registration (RPAR) process, under FIFRA.

1977: NIOSH recommends lowering OSHA's 20 ppm standard for EDB.

1977: EPA publishes notice starting RPAR process for EDB in response to EDF petition.

1978: Final NCI report states that EDB must be considered capable of causing cancer in humans.

1978: The pesticide DBCP is banned, causing increased reliance on the alternative EDB as a pesticide.

1980: Some 53 companies nationwide make 122 products containing EDB.

* This chronology is based primarily on material prepared for the Senate Environment and Public Works Committee.

1980: December 10 - EPA announces availability of first position document setting forth EPA's review of the evidence concerning EDB: "Notice of Preliminary Determination Concluding the RPAR", Position Document 2/3." The Agency concluded that the presumptions of oncogencity, mutagenicity, and reproductive effects were not rebutted, and proposes an end to EDB use except for soil fumigation.

1981: April - EPA has gathered all necessary scientific information on EDB to prepare final RPAR decision.

1981: Internal EPA study finds that at existing maximum levels of permitted exposure, theoretically, 999 workers out of 1000 could contract cancers. EDB risk termed one of the highest EPA has ever confronted.

1981: September - California OSHA proposes a 15 ppb standard for EDB (for EDB vapor in ambient air). Federal OSHA standard is 20 ppm. (California standard over 1000-fold stricter.)

1981: Autumn - White House Office of Science and Technology task force on EDB formed to study problem.

1981: October - NIOSH reaffirms 1977 cancer assessment in letter to OSHA.

1982: June 10 - Draft of EPA Position Document 4 completed - Office of Pesticide Programs completes development of proposed final decision on EDB and forwards to Assistant Administrator Todhunter.

1983: July 27 - Florida bans EDB for use as a soil fumigant.

1983: September 13 - House Education & Labor Subcommittee on Labor Standards holds hearing on EDB workplace hazards.

1983: September 26 - House Government. Operations Subcommittee on Energy, Environment and Natural Resources holds hearing on EPA's Pesticide Registration Activities.

1983: September 27 - Position Document 4 made public, presents Agency's final determination regarding RPAR: suspension order for use of EDB as a soil fumigant; cancellation order for use of EDB as a spot and grain fumigant, and cancellation order for EDB use as a quarantine fumigant, effective 9/1/84.

1983: October 1 - EPA ban on EDB as a soil fumigant goes into effect.

1983: December 20 - Florida orders stop sale of grain-based products with detectable levels of EDB (greater than 1 ppb).

1984: January 4 - Spot checks by Federal agencies find residues of EDB in certain foods around the nation, concern regarding EDB grows.

1984: January 5 - EPA announces it is considering an emergency suspension of grain and milling uses, starting proceedings to revoke 1956 grain tolerance action level exemption, and continuing work on setting a tolerance.

1984: January 9 - California closes its borders to fruit treated with EDB after continuing to detect high levels of contamination in pulp.

1984: January 10 - EPA, USDA, food industry officials, and other senior administration officials hold emergency meeting about growing EDB contamination hazards.

1984: February 3 - EPA announces emergency suspension of grain uses of EDB and recommends acceptable residue levels in raw grain (900 ppb), products requiring further processing before eating (150 ppb), and ready-to-eat products (30 ppb).

1984: March 2 - EPA announces interim tolerance of 250 ppb on citrus and papaya whole fruit, which is equivalent to a 30 ppb level in the edible portions. After September 1, 1984, no EDB residues will be allowed on these products--domestic or imported.