B. The Statute

A pesticide may be sold or distributed in the United States only if it is registered or exempt from registration under FIFRA as amended (7 U.S.C. 136 et. seq.). Before a product can be registered unconditionally, it must be shown that it can be used without 'unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)), that is, without causing "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide" (FIFRA section 2(bb)). The burden of proving that a pesticide meets this standard for registration is, at all times, on the proponent of initial or continued registration. If, at any time, the Agency determines that a pesticide no longer meets this standard for registration, then the Administrator may cancel the registration under section 6 of FIFRA.

C. Regulatory Background

Dichlorvos is an organophosphate insecticide registered for use in controlling flies, mosquitos, gnats, cockroaches, fleas, and other insect pests. Amvac Chemical Corporation is the sole producer of technical grade dichlorvos in the U.S. There are currently 182 product registrations for formulations containing dichlorvos. In addition, there are three section 24(c) Special Local Need Registrations. Formulations include: Pressurized liquids, granulars, dusts, wettable powders, emulsifiable concentrates, total release aerosols, and impregnated materials. Applications are made with aerosols and fogging equipment, with ground spray equipment, and through slow release from impregnated materials, such as resin strips and pet collars.

Dichlorvos has been registered in the U.S. since 1948. The Shell Chemical Company marketed the product under the trademark Vapona, and, in 1963, Shell began marketing the No-Pest Strip. In 1985, approximately 2 million pounds of dichlorvos active ingredient were used annually in the U.S. on a variety of sites. At that time, agricultural applications constituted 60 percent of the total dichlorvos usage, including use on beef and dairy cattle, poultry, sheep, livestock living quarters and other farm buildings, greenhouses, mushroom houses, stored agricultural products, stored food facilities, and tobacco warehouses. In addition, approximately 25 percent was used on commercial, institutional, and industrial sites, including food processing areas, food

handling establishments, sewage and dump sites, lawns, and turf. The remaining 15 percent was applied in and around homes and on pets. These estimates are based on 1985 data and it is believed that dichlorvos usage has declined significantly in recent years (currently 250,000 to 500,000), but not necessarily proportionally across all sites.

Amvac has also notified EPA that it is not supporting uses on the following sites and requests their voluntary cancellation: Rangeland grasses, greenhouse food crops (cucumber, tomato, lettuce, radish), greenhouse non-food crops, tobacco, tobacco warehouses, tomato (post harvest), domestic dwellings (except for impregnated resin strips, total release foggers, and crack and crevice treatment; impregnated resin strips will not be permitted in kitchens); aircraft and buses; food service establishments, including eating establishments (except for non-food service areas); food manufacturing establishments, including bottling plants and frozen food plants (except for non-food manufacturing areas); food processing establishments, including meat, poultry and seafood slaughtering and/or packing plants, and dairy product plants (except for non-food processing areas); and all aerial applications. EPA has published a notice of receipt of voluntary cancellation request for these uses in the Federal Register pursuant to section 6(f) of FIFRA on April 19, 1995 (60 FR 19580).

In 1980, the Agency referred dichlorvos to the Rebuttable Presumption Against Registration or RPAR process under FIFRA, now called the Special Review process. The RPAR referral was based on scientific studies which indicated that dichlorvos was mutagenic and might cause cancer, nerve damage, and birth defects in laboratory animals

laboratory animals. In 1982, the Agency issued a document reporting the results of its evaluation of dichlorvos (47 FR 45075). Initial concern had been based on the results of animal studies that were later found to be equivocal or to show no positive evidence of the suspected effects of exposure to dichlorvos. The Agency concluded that the existing information did not support the initiation of the RPAR process at that time. However, a determination was made to review results of carcinogenicity studies being conducted for the National Cancer Institute/ National Toxicology Program when completed, and to issue a Data Call-In (DCI) for four mutagenicity studies in March 1983.

The Natural Resources Defense Council (NRDC), et al., brought suit against the Agency in 1983, in part, to require a reassessment of several RPAR decisions. A settlement agreement was reached in September 1984, in which the Agency agreed to reassess the pre-RPAR decision on dichlorvos. The parties also agreed that reassessment of dichlorvos would begin once the mutagenicity and carcinogenicity studies were received and evaluated.

The dichlorvos Registration Standard, issued in September 1987, stated that the Agency was considering further regulatory action for all registered uses of dichlorvos. The Registration Standard classified all dichlorvos products as restricted use, except for resin pest strips, pet uses, and all remaining products allowing household use only. The Agency also determined that all products must contain a hazard warning for cancer, liver effects, and cholinesterase inhibition. An interim 48-hour reentry interval was imposed for the agricultural and commercial uses of dichlorvos. The Registration Standard also identified and required additional data necessary to evaluate fully the human and environmental risks associated with the use of dichlorvos as an insecticide.

Amvac Chemical Corporation formally requested that EPA reconsider the requirements for a cancer warning statement and 48-hour reentry interval in February 1988. In September 1988, EPA formally deferred imposition of all Registration Standard label modifications and data requirements pending evaluation of comments and additional data regarding the label requirements, due to uncertainty concerning the cancer classification of dichlorvos. (These data requirements were later reinstated in August 1991 and January 1994.) Registrants were also informed that the Agency would amend the dichlorvos Registration Standard after completion of the reassessment.

On February 24, 1988, EPA initiated a Special Review for pesticide products containing dichlorvos. EPA determined that exposure to dichlorvos from the registered uses may pose an unreasonable carcinogenic risk and inadequate margins of exposure for cholinesterase inhibition and liver effects to exposed individuals. The risks of concern detailed in the Notice were for the general population from consumption of foods containing residues of dichlorvos, for those involved in the application of dichlorvos, for workers reentering treated areas, for residents/occupants of treated areas, for people exposed to pets