ENVIRONMENTAL PROTECTION AGENCY

[OPP–30000/56; FRL–4954–7]

Dichlorvos; Notice of Preliminary Determination to Cancel Certain Registrations and Draft Notice of Intent to Cancel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of preliminary determination.

SUMMARY: This Notice sets forth EPA's preliminary determination regarding the continued registration of pesticide products containing dichlorvos and sets forth the Agency's assessment of the risks and benefits associated with dichlorvos products. This Notice announces the Agency's preliminary determination to propose cancellation of certain registrations of dichlorvos products and to propose modification to other registrations which would not be canceled. In addition, this Notice serves as a Draft Notice of Intent to Cancel.

DATES: Written comments must be received on or before December 27, 1995.

ADDRESSES: Submit three copies of written comments bearing the docket control number ''OPP–30000–56'' by mail to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number ''OPP–30000/56.'' No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit VII. of this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as confidential business information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis Utterback, Special Review and Reregistration Division (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Special Review Branch, 3rd floor, Crystal Station #1, 2800 Crystal Drive, Arlington, VA, Telephone: 703–308–8026: e-mail: utterback.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This Notice is organized into the following units: Unit I. is the introduction which includes background information related to dichlorvos, a description of the Agency's Special Review process, and the regulatory history of dichlorvos (2,2-dichlorovinyl dimethyl phosphate), also known as DDVP, including the initiation of Special Review. Unit II. summarizes the risk assessment. Unit III. summarizes the benefits of dichlorvos uses. Unit IV. explains the Agency's risk/benefit analysis and proposed regulatory decisions. Unit V. describes the Agency's existing stocks policy. Unit VI. describes the procedures related to the referral of this document to the U.S. Department of Agriculture and FIFRA Scientific Advisory Panel. Unit VII. describes the opportunity for public comment, and Unit VIII. describes the availability of information in the Public Docket. Finally, Unit IX. lists references to this document.

I. Introduction

A. Summary

EPA has concluded that the risks outweigh the benefits for most uses of dichlorvos, and therefore, recommends a variety of measures to reduce those risks. Dichlorvos poses carcinogenic risks of concern to the general population from dietary exposure and risks of cholinesterase inhibition (including cholinergic signs) to individuals mixing, loading, and applying this pesticide, as well as to those reentering treated areas. The Agency believes that the economic benefits associated with the continued use of dichlorvos are not significant for most uses. After careful consideration of the risks and benefits, EPA is proposing the following actions: Cancellation of all uses in or on residences, tobacco warehouses, ornamental lawns, turf and plants, commercial, institutional and industrial areas, airplanes, trucks, shipholds, and rail cars, warehouses, and use on bulk, packaged or bagged nonperishable processed and raw food (except for impregnated resin strips in silos). In addition, EPA is proposing to cancel other registrations unless certain modifications are made to the label, including: prohibit hand-held application in mushroom houses, greenhouses, on food and nonfood animals (other than poultry), and in passenger buses; allow other application methods in mushroom houses, greenhouses or passenger buses, as long as the applicator and others are prohibited from remaining in these facilties during treatment; restrict all remaining registered products to use by certified applicators only, except for impregnated resin strips used in museums (closed spaces) and in insect traps, and require personal protective equipment (PPE) during handling; and require reentry intervals for mushroom houses, greenhouses and passenger buses. EPA is proposing to retain the following uses: mushroom houses and greenhouses (only automatic foggers or fogging through a port, and restricted reentry), kennels, feedlots, insect traps, garbage dumps, direct application to poultry, automated application to livestock, animal premises, manure, and buses (fogger use).

In addition to the Special Review, there are three activities which may affect dichlorvos registrations. First, EPA published the Final Revocation Notice for the food additive regulation (FAR) of dichlorvos residues on packaged or bagged nonperishable processed food in the Federal Register of November 10, 1993 (58 FR 59667). The effective date of this Notice was stayed indefinitely. Second, if that revocation becomes effective, under current policy, EPA would issue a notice of its intent to cancel the related uses under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Third, EPA received a request from Amvac Chemical Corporation, the sole technical registrant of dichlorvos, to voluntarily delete several uses from its technical label. EPA intends to accept Amvac's request unless the Company withdraws or modifies its request.

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.

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

treated with dichlorvos, and for pets treated with dichlorvos.

On May 25, 1989, the State of California, NRDC, Public Citizen, the AFL-CIO, and several individuals filed a petition which asked the Agency to revoke FARs for seven potentially carcinogenic substances, including FARs for residues of dichlorvos in or on dried figs, and on packaged or bagged nonperishable processed food. The petitioners argued that these FARs should be revoked because the seven pesticides to which the regulations applied were animal carcinogens and thus the regulations violated the Delaney clause of section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). The Delaney clause provides that a FAR may not be approved for a food additive if it ''is found to induce cancer when ingested by man or animal. . . .'' 21 U.S.C. 348(c). In responding to the petition, EPA reiterated its 1988 interpretation that the Delaney clause is subject to an exception for pesticide uses which posed no greater than a *de minimis* cancer risk (56 FR 7750, February 25, 1991). Although EPA concluded that several of the challenged regulations met this *de minimis* standard, EPA found that the dichlorvos FAR for packaged or bagged nonperishable processed food did not meet this standard.

Therefore, in the Federal Register of October 3, 1991 (56 FR 50190), EPA proposed to revoke the FAR for residues of the pesticide dichlorvos on packaged or bagged nonperishable processed food, under section 409 of the FFDCA. Subsequent to that Notice, on July 8, 1992, in, *Les v. Reilly*, 968 F.2d 985 (9th Cir.), the Ninth Circuit Court ruled that the Delaney clause was not subject to an exception rule for those pesticides that pose a *de minimis* cancer risk. Following the Ninth Circuit Court decision, EPA revoked the section 409 FAR of dichlorvos on packaged or bagged nonperishable processed food (58 FR 59663, November 10, 1993) on the basis that it was in violation of the Delaney clause. EPA later stayed the 120–day effective date indefinitely, pending Agency consideration of a request for a hearing from Amvac. Legal pesticide residues on food are permitted by FFDCA; however, the use of a pesticide is permitted separately under FIFRA. Because the revocation was stayed, residues in food are currently allowed. When the stay is lifted, pesticide residues will be illegal; however, the use of dichlorvos will still be permitted under FIFRA. Therefore, under current policy, EPA intends to cancel the related uses as soon as possible after the FAR revocation becomes final. That cancellation will prevent the potential situation in which foods legally treated with dichlorvos under FIFRA would be considered adulterated and subject to seizure under FFDCA.

In August 1991, EPA reimposed indoor use data requirements that were required in the 1987 Registration Standard, and were deferred in 1988. These data have since been submitted by Amvac and reviewed by the Agency, and are used in the risk assessment presented here. In addition, the 1987 residential outdoor and terrestrial non-food use data requirements were reimposed on January 3, 1994. Another DCI was issued on February 22, 1994, for additional studies to support terrestrial non-food and residential outdoor uses. EPA has received some studies as a result of this DCI and the last study is due in March 1996. A further DCI was issued on November 10, 1994, for residue data relating to crack and crevice treatment around packaged and bagged food.

Based on information received in public comments and on additional analyses performed since the Special Review process began, EPA is now issuing this Notice of Preliminary Determination. Issuance of this Notice means that the Agency has assessed the potential adverse effects and the benefits associated with the use of pesticide products containing dichlorvos and that the Agency has preliminarily determined that, unless the terms and conditions of registration are modified as proposed in this Notice, the risks from the use of dichlorvos outweigh the benefits of their continued use.

EPA's position and a summary of the rationale underlying that position are set forth in this Notice. The basis for EPA's action is explained more fully in documents contained in the dichlorvos docket. The docket also contains references and background information pertinent to the registration of pesticide products containing dichlorvos.

This Notice serves both as a preliminary determination of the Special Review process and as a draft Notice of Intent to Cancel dichlorvos registrations. FIFRA requires that a draft Notice of Intent to Cancel be prepared and forwarded to the Scientific Advisory Panel (SAP) and the Secretary of the United States Department of Agriculture (USDA) to permit their review of the Agency's proposed action. The draft Notice of Intent to Cancel is not now legally effective but is intended only to provide a basis for comment by the SAP, USDA, registrants, and the public. EPA's compliance with this review requirement is discussed in Unit VII. of this Notice. Comments on this preliminary determination and Draft Notice of Intent to Cancel must be filed within 90 days of the issuance of this Notice.

II. Risk Assessment

A. Summary of Risk Assessment

Risk assessment is the process used to estimate the likelihood and magnitude of health effects that result from environmental exposures. This process consists of the following four components: Hazard identification, dose-response assessment, exposure assessment, and risk characterization. The first component, hazard identification, is a determination whether a particular chemical is or is not causally linked to particular adverse health effects. Dose-response assessment estimates the amount of a chemical that could potentially cause an adverse health effect. The amount of a chemical that did not result in an observable or measurable effect in an animal study is the no-observed-effect level (NOEL). All substances can cause a toxic effect at some level. The extent to which a chemical is toxic depends on the amount of the chemical needed to produce the adverse effect. Low toxicity chemicals require a large amount of the chemical to produce the adverse health effect, while highly toxic chemicals require only a small dose to produce the toxic effect. Exposure assessment describes the level or magnitude of exposure to the chemical, the route of exposure (inhalation, dermal, or oral), and the frequency of the exposure. Finally, risk characterization involves describing the nature and magnitude of human risk. The dose-response and exposure assessments are combined to estimate some measure of human risk. The potential for possible non-cancer health effects in humans is generally expressed as the margin of exposure (MOE) which is the ratio of the NOEL (dosage producing no effects) to the estimated exposure. For cancer, the risk is expressed as a probability of developing cancer over a lifetime, which is based on exposure and the chemical's cancer potency. The risk characterization component also summarizes the major strengths and weaknesses of the risk assessment.

In the case of dichlorvos, the Agency has determined that the adverse effects of primary concern for dichlorvos are those related to cancer and inhibition of cholinesterase activity including cholinergic signs (clinical signs indicative of cholinesterase inhibition in test animals). Based on data from

several carcinogenicity studies, the Agency has concluded that dichlorvos meets the criteria for a Group C (possible human) carcinogen. Dichlorvos has been shown to induce forestomach tumors in mice and leukemia in rats. Results from acute/short-term, subchronic and chronic toxicity studies have shown dichlorvos to be a potent inhibitor of plasma, red blood cell and brain cholinesterase in several mammalian species, and to produce cholinergic signs.

In the Notice initiating the Special Review, EPA estimated cancer risks for those individuals potentially exposed to dichlorvos through dietary and non-dietary (i.e. inhalation and dermal contact) routes. Since that time, EPA has determined that it is not appropriate to extrapolate from oral carcinogenicity data for estimation of excess individual cancer risks for exposure by the dermal and inhalation routes. Therefore, cancer risk estimates for workers and residents exposed to dichlorvos by the dermal and inhalation routes are not included in this revised risk assessment. EPA only estimated excess individual lifetime cancer risks for dietary exposure to the general population.

Dietary exposure to dichlorvos residues may occur as a result of use on a variety of sites, including greenhouse food crops, mushroom houses, bulk-stored and packaged or bagged nonperishable processed and raw food, commercial food processing plants, groceries, eating establishments, and direct animal treatment. Some of these exposures and resulting risks may be eliminated due to voluntary cancellations or cancellation of uses related to the revocation of the FAR for packaged or bagged nonperishable processed food; however, since these actions are not final yet, for purposes of this document, EPA will assume that these uses will continue. EPA estimates dietary cancer risks from registered uses of dichlorvos to be 4.4 x 10^{-6}. The major source of this estimated risk is from consumption of bulk, packaged or bagged nonperishable raw and processed food treated with dichlorvos (3.4 x 10^{-6}).

In addition to registered uses of dichlorvos, naled provides an additional source of dietary risk from dichlorvos. Naled, an insecticide, is metabolized to dichlorvos by plants. As a result, the Agency felt it appropriate to characterize the total risk from dichlorvos even though naled itself is not under Special Review. The combined dietary cancer risk from dichlorvos is 5.1 x 10^{-6} which includes risk directly from dichlorvos (4.4 x 10^{-6}) and from naled-derived dichlorvos (7.2 x 10^{-7}).

EPA completed a series of exposure assessments in 1987 for the Registration Standard and PD 1 that estimated the exposure to individuals mixing, loading and applying dichlorvos, as well as to those reentering areas treated with dichlorvos. These estimates were based on the best available data, which in most cases were exposure data derived from other pesticides applied in a similar manner as dichlorvos. Additional exposure data have been submitted since that time and the Agency has determined that revisions to the original assessments are appropriate based on these new data. EPA has revised its original exposure estimates for several uses of dichlorvos, including: Crack and crevice application, greenhouses, mushroom houses, dairy barns and milk rooms, household aerosol and total release fogger products.

Red blood cell, plasma and brain cholinesterase inhibition and/or cholinergic signs are the basis for the short-term, intermediate, and long-term MOE estimates. For pesticides, EPA classifies occupational/residential exposure patterns as short-term (1 to 7 days), intermediate (1 week to several months per year), or long-term (a substantial portion of the lifetime). These scenarios could vary by region or from year-to-year depending on the severity of the pest problem. Separate NOELs were selected from acute (0.5 mg/kg/day), subchronic (0.1 mg/kg/day), and chronic (0.05 mg/kg/day) toxicity studies to estimate MOEs for varying durations of exposure. Margins of exposure are outlined in Table 1 in Unit II. of this document for individuals reentering treated facilities and for individuals exposed during the application of dichlorvos. Most of the MOEs are below the level which the Agency believes is protective of public health (100).

B. Effects of Concern

1. *Carcinogenicity*. EPA has determined that the risk criteria for carcinogenicity as set forth in 40 CFR 154.7 (a)(2) has been exceeded for dietary exposure. Based on the studies described below, EPA has classified dichlorvos as a Group C (possible human) carcinogen (Ref. 1) .

i. Hazard identification. In July 1987, the Office of Pesticide Program's Carcinogenicity Peer Review Committee (CPRC) classified dichlorvos as a Group B2 (probable human) carcinogen, based primarily on the results of National Toxicology Program (NTP) studies in mice and rats. Since that time, EPA has reevaluated the carcinogenic potential of dichlorvos and concluded that dichlorvos is a Group C (possible human) carcinogen. The basis for that determination is summarized below.

(a) Mouse study. Dichlorvos was administered by gavage to B6C3F1 mice (60/sex/group) for 103 weeks (5 days/week) using corn oil as the vehicle (Ref. 2). Doses were 0, 10, or 20 mg/kg/day for male mice and 0, 20, or 40 mg/kg/day for females. Administration of dichlorvos to female mice was associated with a statistically significant dose-related trend and statistically significant increase in squamous cell forestomach papillomas and combined squamous cell forestomach papillomas and carcinomas at the high-dose. The forestomach tumors were outside the historical control range. In male mice, an increase in squamous cell forestomach papillomas was associated with a significant dose-related trend, but was not statistically significant by pairwise comparison at either dose level. No other tumor types were identified in this study. No malignant squamous cell tumors were found in the historical controls.

(b) Rat study. Dichlorvos was administered, with corn oil as the vehicle, by gavage to F344 rats (60/sex/group) for 103 weeks (five days/week) (Ref. 3). The dosages were 0, 4, or 8 mg/kg/day. The study resulted in a statistically-significant increase in mononuclear cell leukemia in males by pairwise comparison at both dosage levels. The increase in leukemia also exhibited a statistically significant positive dose-related trend. There was an increased incidence of lung adenomas in high-dose male rats which was significant only for a dose-related trend. In addition, dichlorvos administration was associated with a statistically significant increased incidence of mammary gland adenomas and all mammary gland tumors at the low-dose only (by pairwise comparison) in rats. However, the incidence of lung adenomas and mammary gland tumors were within the historical control range.

(c) Reexamination of cancer classification. The FIFRA Scientific Advisory Panel (SAP) reviewed the CPRC's Group B2 cancer classification and concluded that dichlorvos should be classified as a Group C (possible human) carcinogen since: (1) only benign tumors were induced by dichlorvos; (2) they were not dose-related; and (3) dichlorvos was not mutagenic in *in vivo* assays (although it was mutagenic in several *in vitro* test systems with and without metabolic activation) (Ref. 4).

The CPRC met for a second time on September 29, 1987, to examine the issues raised by the SAP with respect to the classification of the carcinogenicity of dichlorvos (Ref. 5). Upon reconsideration, the Committee concluded that the results of the NTP studies indicate that dichlorvos demonstrates sufficient evidence of carcinogenicity in the male rat and female mouse to confirm the initial classification of dichlorvos as a Group B2 carcinogen.

The committee concluded that ''the results of the NTP bioassays indicate that DDVP demonstrates sufficient evidence of carcinogenicity in the male rat and in the female mouse since: (1) A dose-response relationship of statistical significance was seen for pancreatic adenomas (which have the potential to progress towards malignancy) and mononuclear cell leukemia in male rats, (2) a dose-response relationship of statistical significance was seen in the female mouse for forestomach squamous cell papillomas which have the potential to progress to carcinomas, (3) the presence of some forestomach carcinomas (which are rare) was seen in the female mouse, (4) a significant positive trend was seen for forestomach papillomas in male mice at a dose that did not achieve an MTD, (5) supporting evidence provided by a statistically significant increase in mammary tumors at the low dose in the female rat which was associated with a significant trend, and (6) mutagenicity data was available indicating that DDVP is positive for mutagenicity *in vitro* in bacterial and mammalian cells both with and without metabolic activation. The Committee, thereby, confirmed their initial classification of DDVP as a B2 oncogen.''

The CPRC had a third meeting on June 2, 1988, to review the conclusions of an April 1988 meeting of NTP Panel of Experts on the carcinogenic classification of dichlorvos (Ref. 6). Scientists at NTP had resectioned the pancreas of all test groups in the rat bioassay. The additional sectioning of pancreata resulted in an increased number of tumors in the control animals, thus diminishing the statistical significance of this lesion. Based on this finding, the NTP scientists concluded that the evidence for carcinogenicity in male rats should be downgraded from *clear evidence* to *some evidence*. The CPRC considered the NTP's information and concluded that dichlorvos should remain classified as a Group B2 carcinogen, because: (1) The incidence of mononuclear cell leukemia in dichlorvos treated F344 rats was treatment-related; (2) although the results of longitudinal sectioning of the pancreas diminished the significance of the pancreatic acinar adenomas in male rats, the incidence of animals with multiple adenomas was still increased with dichlorvos treatment; and (3) dichlorvos is a direct acting mutagen. The Committee considered this as an interim classification until the following additional data had been reviewed: (1) the results of a Japanese study in which dichlorvos was administered in drinking water to Fischer 344 rats and B6C3F1 mice; (2) additional data on a chronic rat inhalation study; (3) additional *in vivo* mutagenicity data, and (4) additional historical control information on pancreatic acinar adenomas.

The CPRC met for a fourth time on July 19, 1989, the conclusions of which serve as the basis for the cancer hazard assessment in this proposed determination (Ref. 7). The purpose of this meeting was to reconsider the NTP rat study in light of the recent NTP Panel of Experts report, evaluate new oncogenicity studies with DDVP administered by inhalation or in drinking water and consider other ancillary information.

As mentioned earlier, the NTP reexamined the pancreata of male and female rats using longitudinal sections which diminished the statistical significance of this lesion. The NTP analysis of the combined data indicated a statistically significant difference between the treated and control groups with a positive dose-related trend using the logistic regression analysis. However, EPA scientists concluded that the increase in pancreatic acinar tumors was neither significant in the Fischer Exact test for pairwise comparison, nor positive in the Cochran-Armitage test for dose-related trend, which are typically used for testing dose groups having no survival disparities. The incidence of animals with multiple pancreatic adenomas was still increased with dichlorvos treatment and outside of the historical control range.

The Committee also reevaluated an inhalation oncogenicity study in which 50 CFE rats/sex/dose were exposed to concentrations of 0.05, 0.5 or 5.0 mg/m^3 of technical dichlorvos 23 hours per day for 2 years. This study was reviewed for the dichlorvos Registration Standard and the Agency considered the study inadequate for evaluating the carcinogenicity of the chemical. The study was upgraded after the individual animal data were submitted to the Agency. Agency scientists have concluded that administration of dichlorvos did not alter the tumor incidence in this study.

In addition to the Japanese drinking water study in Fischer 344 rats, Amvac Chemical Corporation submitted a study to the Agency in March 1989, using B6C3F1 mice which was also conducted in Japan. In both studies, dichlorvos was administered in drinking water for 2 years. The CPRC considered both studies to be deficient in conduct and reporting, including incomplete histopathologic evaluation, absence of water consumption data, and failure to include individual animal data in the final report. As a result of these deficiencies, the studies are not amenable to statistical analyses. However, the studies are useful in identifying a qualitative trend in that dichlorvos treatment induced some tumors similar to those induced in the oral gavage studies. In the rat study, there appeared to be an increased incidence of mononuclear cell and lymphocytic leukemia in treated males, as well as mammary gland fibroadenomas in females. In the mouse study, there appeared to be an increased incidence of fibrous histiocytomas and thymomas in males.

The Committee agreed, based upon the available information to reclassify dichlorvos as a Group C carcinogen, in accordance with the Agency's Guidelines for Carcinogenic Risk Assessment. This downgrading from the previous classification as Group B2 was due to: (1) Erosion of the evidence on the pancreatic acinar adenomas in male rats; (2) upgrading and consideration of the negative inhalation study in CFE rats; and (3) questions regarding the biological significance of the primary tumors in the NTP studies, i.e., leukemia in rats (variable tumors in historical controls) and forestomach tumors in mice and its relevance to man.

ii. Weight-of-the-evidence for carcinogenicity. In its most recent evaluation, the fourth cancer peer review, the CPRC considered the weight-of-the-evidence and concluded that dichlorvos should be classified as a Group C (possible human) carcinogen based on inadequate human data and limited data from animal bioassays. The Group C classification is supported by the following points:

(a) In B6C3F1 mice, dichlorvos induced a statistically significant increase in forestomach squamous cell papillomas and combined forestomach squamous cell carcinomas and papillomas in high-dose females. This tumor-type (squamous cell papillomas) was also increased in high-dose males but was significant only for a positive dose-related trend.

(b) In Fischer 344 rats, dichlorvos was associated with a statistically significant increase, with a positive dose-related trend, in leukemia (of all sites and types) in males at both dosage levels. This evidence is supported by the results of the transplantable rat mononuclear cell leukemia model. The treatment was also associated with a numerical (not statistically significant) increase in pancreatic acinar adenomas in males. The incidence of animals with multiple pancreatic acinar adenomas was also increased.

(c) The Group C classification is further supported by studies indicating that dichlorvos is a direct acting gene mutagen in bacteria, fungi and mammalian cells *in vitro*, and suggesting *in vivo* mutagenic activity. (Refs. 8-17). Dichloroacetaldehye, a product of hydrolytic or oxidative cleavage of dichlorvos, has also been reported to be mutagenic in the scientific literature (Ref. 18). Additionally, dichlorvos is structurally similar to known chemical mutagens/carcinogens (i.e., tetrachlorvinphos and phosphamidon).

iii. Dose-response assessment. The CPRC concluded that a quantitative estimate of the carcinogenic potency should be performed for dichlorvos. Cancer potency (or Q_1*) is a quantitative estimate of the relationship between exposure to increasing doses of a chemical and the chemical's ability to induce tumors (i.e., increased number of tumors per unit dose). Because most animal studies do not include a sample size large enough to detect carcinogenic responses at low doses comparable to environmental exposures, the Agency normally estimates the cancer potency of a chemical by extrapolating from responses in high-dose animal experiments.

Several mathematical models have been developed to estimate the cancer potency. In the absence of information demonstrating a more appropriate model, the Agency generally uses the linearized multi-stage model to extrapolate from effects seen at high-doses in laboratory studies to predict tumor response at low-doses. This model is based on the biological theory that a single exposure to a carcinogen can initiate an irreversible series of transformations in a single cell that will eventually lead to a tumor. In addition, the linearized multi-stage model assumes that the probability of each transformation is linearly related to the degree of exposure (i.e., a threshold does not exist for carcinogenicity).

Using this model, the Agency estimated the cancer potency (Q_1*) for dichlorvos based on the tumor incidence data in female mice and male rats in the NTP studies. The cancer potency in human equivalents is 1.22×10^{-1} $(mg/kg/day)^{-1}$, which is the geometric mean of the Q_1* for female mouse forestomach tumors and the Q_1* for leukemia in male rats (Ref. 19). The Q_1* represents the 95 percent upper confidence limit of tumor induction likely to occur from a unit-dose.

The CPRC (fourth cancer peer review) also recommended not to quantify the cancer risk by a low-dose extrapolation model for the inhalation route of exposure. The primary basis for this recommendation was the upgrading of a 2-year inhalation study in rats which did not result in an increased tumor incidence. The recommendation was based on the following considerations: The quality of the oral cancer data, the route specificity of the target organs, the reliability and accuracy in estimating the target-dose and the unlikelihood that exposure via the inhalation route would lead to the formation of a reactive metabolite.

In addition, the OPP Reference Dose Committee concluded that extrapolating the results from the oral gavage studies to the dermal route of exposure is not appropriate for dichlorvos (Ref. 20). This decision was based on the following considerations: (1) There was no dose-response relationship in the leukemia observed in male Fisher 344 rats; (2) the tumors observed in female B6C3F1 mice were contact site tumors, the relevance of which to humans is unknown, and the incidence of which, at all dose levels, including the concurrent controls, was outside the National Toxicology Program's control range; (3) the dynamics of absorption, distribution, metabolism and excretion do not favor retention of the chemical in animal tissues and makes it difficult to determine accurately the concentration at the target site; and (4) it is not expected that topically applied doses would reach the target organ(s) in sufficient quantity to produce a carcinogenic response or would be sufficient to alkylate macromolecules in the target tissues to produce contact site tumors. Therefore, extrapolation from oral data to dermal or inhalation routes is not appropriate, for estimation of excess individual cancer risk, for exposure to dichlorvos.

2. *Cholinesterase inhibition*. Cholinesterase (ChE) refers to a family of enzymes that are essential to the normal functioning of the nervous system. These enzymes are necessary for the transmission of nerve impulses. Inhibition of ChE activity can result in a number of cholinergic signs and symptoms in humans, depending on the rate and magnitude of exposure, including: Headaches, dizziness, nausea, vomiting, diarrhea and increased urination, blurred vision, pinpoint pupils, increased salivation, labored breathing, muscle paralysis, slow heart rate, respiratory depression, convulsions, coma and even death. These enzymes have been identified in nearly every tissue of the body; however, ChE activity is usually measured in blood plasma and red blood cells in humans, while ChE levels in laboratory animals are measured in plasma, red blood cells as well as brain tissue.

Organophosphate pesticides, such as dichlorvos, are known to inhibit ChE activity and some cause delayed neurotoxic effects. EPA has evaluated the available information and concluded that dichlorvos is a potent ChE inhibitor. This determination is based on toxicological data using laboratory animals, human poisoning incidents, and limited human toxicity information, which are discussed below.

i. Laboratory data. Acute, subchronic and chronic laboratory studies using experimental animals have shown dichlorvos to be a potent ChE inhibitor, significantly reducing blood plasma, red blood cell and brain ChE. ChE inhibition has been demonstrated in several mammalian species following oral, inhalation, and dermal administration of dichlorvos. Only the primary studies selected for use in assessing risk from short-term, intermediate, and long-term exposures are discussed below.

(a) Acute toxicity data. Acute neurotoxicity data are limited in comparison to available subchronic and chronic data, but are more relevant for assessing risk from single and short-term repeated exposure scenarios. Acute neurotoxicity studies have been conducted in both hens and rats. An acute neurotoxicity study in rats evaluated the neurobehavioral signs and the neuropathological effects following single exposures, but did not measure ChE inhibition (Ref. 21). Groups of 12 male and female Sprague-Dawley rats were administered single oral doses of 0, 0.5, 35 or 70 mg/kg/day by gavage. At the mid- and high-doses, administration of dichlorvos resulted in a variety of neurological and physiological changes (e.g., alterations in posture, mobility and gait, reduced or absent forelimb/hindlimb grasp, tremors). Most of these changes were observed about 15 minutes after compound administration, while no toxicity was apparent for the survivors (there were several deaths at the high-dose) 7 days following administration of dichlorvos at all dose

levels. Based on the study results, the NOEL for signs associated with ChE inhibition was established at 0.5 mg/kg/day.

An acute delayed neurotoxicity study in hens resulted in cholinergic signs of ChE inhibition and neuropathic effects (Ref. 22). Ten birds were administered a single dose of 16.5 mg/kg/day by oral intubation. The test birds were given another oral dose at 21 days and observed for an additional 21 days. Dichlorvos-treated birds demonstrated signs of ChE inhibition shortly after dosing, including: lethargy and depression, incoordination, limb weakness, wing drop, and reduced reaction to external stimulation. The birds were asymptomatic by day 3 after dosing. Administration of dichlorvos did not produce overt signs of acute delayed neurotoxicity, but neuropathic effects (peripheral nerve lesions which are associated with paralysis) did occur in one hen. A NOEL was not shown for this effect in this one dose study.

Additional information about short-term exposure is provided by a range-finding study in which dogs (one male and one female for each dose) were administered dichlorvos by capsule for 2 weeks at the following doses: 0, 0.1, 1.0, 5.0, 10, 15, 30, or 60 mg/kg/day (Ref. 23). Plasma and red blood cell ChE levels were decreased in the 1.0 mg/kg/day group and above as early as 6 days after dosing. The degree of ChE inhibition increased with dose. During the first week following dosing, severe cholinergic signs were observed in animals at 30 and 60 mg/kg/day and death occurred at these doses during the second week of dosing. However, this study is not appropriate for short-term risk assessment because only a limited number of animals were treated at each dose and dichlorvos was administered repeatedly. This study indicates that short-term exposure to dichlorvos at low levels produces ChE inhibition in plasma, red blood cells and brain tissue, and contributes to the overall weight-of-the-evidence.

(b) Subchronic toxicity data. A study was performed in rats providing ChE inhibition data following subchronic exposure to dichlorvos (Ref. 24). Groups of 10 male and 10 female rats were administered doses of 0, 0.1, 1.5 or 15 mg/kg/day by oral gavage for 13 weeks (5 days/week). Observations recorded approximately 30 to 60 minutes post-dose included salivation in 7 males and 4 females treated with 15 mg/kg/day. Urine stains were also seen in 7 males and 5 females at this dose. These observations were seen on certain days during weeks 6 through 12 for males and 8 through 12 for females. At week 7, plasma ChE activity was significantly reduced in mid- and high-dose male and high-dose female rats when compared to the controls. Mid- and high-dose male and female rats also demonstrated significantly reduced red blood cell (RBC) ChE activity when compared to the controls at 7 weeks. At the 14–week interval, plasma ChE activity was significantly reduced in high-dose males and females, while RBC activity was significantly lower than controls in mid- and high-dose animals. Red blood cell ChE activity was also reduced in low-dose (0.1 mg/kg/day) females at 14 weeks; however, the RBC ChE inhibition was not considered biologically significant since it was less than 10 percent below ChE activity in control animals. Brain ChE activity in high-dose female rats was 49 percent lower than in control females and was statistically significant, while brain ChE activity in high-dose males was reduced 28 percent below control males but inhibition was not statistically significant. The data presented support a NOEL of 0.1 mg/kg/day based on plasma and red blood cell ChE inhibition at doses of 1.5 mg/kg/day and above.

An additional subchronic study in rats evaluated neurobehavioral signs, neuropathological effects, and also measured ChE activity (Ref. 25). Dichlorvos was administered by oral gavage to male and female rats at doses of 0, 0.1, 7.5, or 15 mg/kg/day (15 animals/sex/dose) for 90 days. There were no significant differences between the control and treated animals with respect to the functional observational battery or locomotor activity evaluations, nor were any neuropathological lesions attributable to dichlorvos. However, administration of dichlorvos was accompanied by cholinergic signs (tremors, salivation, exophthalmos, lacrimation) approximately 15 minutes after dosing in the high-dose animals and, to a lesser extent, in the mid-dose animals. In general, cholinergic signs occurred during the first dosing week in high-dose animals and during the third dosing week in mid-dose animals and persisted to study termination in both groups. Plasma ChE inhibition was statistically significant at all time periods measured; however, RBC ChE inhibition was only statistically significant for high-dose males at week 3. ChE levels in RBC were reduced 23, 12, and 18 percent in the mid-dose males and 35, 8, and 11 percent in the high-dose males compared to controls during weeks 3, 7, and 13, respectively. In females, RBC ChE inhibition of 13, 38, and 33 percent at the mid-dose, and of 4, 42, and 35 percent at the high-dose were noted during weeks 3, 7, and 13, respectively. Brain stem and brain cortex ChE activity were also reduced from 11 to 12 percent in low-dose animals and from 10 to 16 percent in high-dose rats as compared to controls. Inhibition of brain stem ChE activity was statistically significant in high-dose males only, while in the cerebral cortex ChE was significantly reduced for animals in the mid- and high-dose groups. The NOEL from this study was 0.1 mg/kg/day based on ChE inhibition (plasma, RBC, brain) and cholinergic signs occurring at 7.5 mg/kg/day.

A developmental toxicity study in New Zealand white rabbits produced signs of ChE inhibition at similar dose levels as the subchronic rat studies (Ref. 26). Groups of 16 pregnant females were administered doses of 0, 0.1, 2.5, or 7.0 mg/kg/day by oral gavage on gestation days 7 through 19, inclusive. The doses were selected based on the results of a range-finding study conducted in the same strain of pregnant rabbits at dose levels of 0, 0.1, 1.0, 2.5, 5.0 or 10 mg/kg/day (8 per group, except for 7 in the 2.5 mg/kg/day group) in which there were statistically significant reductions in maternal plasma and RBC ChE activity in a dose-related manner at all doses except 0.1 mg/kg/day. Profound treatment-related maternal mortality (5/8 died) and cholinergic signs occurred at 10 mg/kg/day. In the definitive developmental toxicity study, mortality was observed at 2.5 mg/kg/day (13 percent) and 7.0 mg/kg/day (25 percent). ChE inhibition was not measured; however, apparent anticholinesterase-related signs and symptoms were observed at the high-dose, including ataxia, prone positioning, tremors, excitation, salivation, diarrhea and difficulty in breathing. Based on the range-finding and definitive study results, the maternal toxicity NOEL and Lowest Effect Level (LEL) were demonstrated at 0.1 and 2.5 mg/kg/day, respectively.

An inhalation developmental toxicity study in rabbits produced findings similar to those of the oral developmental toxicity study (Ref. 27). Groups of 20 female Dutch rabbits were exposed to 0, 0.25, 1.25, or 6.25 μg/L of dichlorvos for 23 hours per day, from day 1 of mating to gestation day 28. No cholinergic signs were noted at 0, 0.25, or 1.25 μg/L, but severe toxicity and mortality occurred after the 6th day of exposure to 6.25 μg/L. Cholinergic signs observed included anorexia, lethargy, muscular tremors, mucous nasal discharge and diarrhea. Sixteen of the 20 does at the high-dose died or were killed because of intoxication. There

were statistically significant reductions in plasma, RBC and brain ChE activity at 1.25 and 6.25 µg/L, while at 0.25 µg/L ChE activity was depressed less than 15 percent. The NOEL for this study is 0.25 µg/L based on ChE inhibition in plasma, RBC and brain tissue. The NOEL of 0.25 µg/L corresponds to approximately 0.14 mg/kg/day. In converting from µg/L to mg/kg/day, EPA assumed that 100 percent of the dichlorvos vapor is absorbed by inhalation and also that the rabbit breathing rate is constant over time.

Additional information on neuropathological effects can be drawn from a 28-day delayed neurotoxicity study in hens, from which preliminary results were submitted to the Agency (Ref. 28). This study was required based on the results of the acute study in hens discussed above. Groups of 21 hens were administered dichlorvos orally at doses of 0, 0.3, 1.0, or 3.0 mg/kg/day for 28 days. These data suggest that significant axonal degeneration in the spinal cord occurred following oral administration of 1 and 3 mg/kg/day, while at 0.3 mg/kg/day only minor effects were noted. While such findings must be regarded as preliminary, they should be regarded as potentially serious, since such lesions represent an irreversible and relatively serious effect. In addition, this report notes that significant (34 to 63 percent) brain ChE inhibition was seen at 1 and 3 mg/kg/day. The final report was submitted to the Agency and is currently under review.

(c) Chronic toxicity data. Both oral and inhalation toxicity data demonstrate that long-term exposure to dichlorvos results in plasma, RBC, and brain ChE inhibition. In a chronic rat inhalation study, groups of 50 male and 50 female CFE rats per dose level were exposed to 0, 0.05, 0.48, or 4.7 mg/m^3 of dichlorvos for 2 years (Ref. 29). There was a statistically significant decrease in ChE activity in plasma, red blood cells, and brain in the mid- and high-dose groups (76, 72, 90 percent and 83, 68, 90 percent of control activity in mid-dose males and females; and 38, 4, 21 and 22, 5, 16 percent of control activity in high-dose males and females, respectively). Red blood cell ChE was reduced to 88 percent of control activity in females dosed at 0.05 mg/m^3, but this decrease was not statistically significant. The NOEL was established at 0.05 mg/m^3 based on ChE inhibition in plasma, red blood cells and brain tissue. The concentration of 0.05 mg/m^3 corresponds to approximately 0.055 mg/kg/day, assuming a constant breathing rate in rats and 100 percent absorption of dichlorvos vapor.

Groups of 4 male and 4 female dogs were administered dichlorvos by capsule 7 days per week at doses of 0, 0.05 (0.1 for the first 3 weeks of study), 1.0 or 3.0 mg/kg/day for 1 year (Ref. 30). Plasma ChE was inhibited (21.1 to 66.6 percent) in males and females in the 0.1, 1.0, and 3.0 mg/kg/day groups during week 2. The low-dose was consequently reduced to 0.05 mg/kg/day on day 22 due to the plasma ChE inhibition (26 percent in females) noted after 12 days of dichlorvos administration. Red blood cell ChE was only slightly decreased (less than 2 percent) in the 0.1 mg/kg/day group at week 2, while animals in the 1.0 and 3.0 mg/kg/day groups exhibited RBC ChE inhibition of 33 to 75 percent. Statistical analyses were not conducted prior to week 13. Statistically significant depression in plasma and RBC ChE occurred at week 13 in males and females in the 1.0 and 3.0 mg/kg/day groups. In addition, brain ChE was significantly reduced in males and females in the high-dose group and in the males of the mid-dose group at termination. Brain ChE activity was inhibited approximately 22 percent in males in the 1.0 mg/kg/day group and 47 percent and 29 percent, respectively, in males and females in the 3.0 mg/kg/day group compared to controls. Study results correspond to a NOEL of 0.05 mg/kg/day, based on plasma, RBC, and brain ChE inhibition.

A two-generation reproductive study was conducted in which Sprague-Dawley rats were exposed via the drinking water to dichlorvos at concentrations of 0, 5, 20, or 80 ppm (males - 0.5, 1.9 or 7.2 mg/kg/day; females - 0.6, 2.3, or 8.3 mg/kg/day) (Ref. 31). ChE assays (plasma, RBC and brain) were performed on males and females of both the F_0 and F_1 generations at terminal sacrifice. The data indicate that RBC ChE was inhibited in both males and females at all doses and in a dose-related manner. At the low-dose, RBC ChE activity was decreased 7 to 14 percent in males and 17 to 23 percent in females. RBC ChE inhibition was statistically significant for both males and females at all dose levels, except for the F_0 males at 0.5 mg/kg/day (7 percent inhibition). Plasma ChE inhibition was statistically significant for both males and females at the mid- and high-dose levels. The plasma ChE inhibition for F_1 males at the low-dose (0.5 mg/kg/day) was also statistically significant (15 percent). In addition, brain ChE activity was inhibited in males and females of both generations at all dose levels. Statistically significant reductions occurred only at the mid- and high-doses. The study results establish a NOEL of less than 5 ppm for RBC and plasma ChE inhibition (males - 0.5 mg/kg/day; females - 0.6 mg/kg/day).

ii. Human data—(a) Toxicity data. EPA reviewed several studies in the scientific literature that measured ChE inhibition in humans following exposure to dichlorvos (Ref. 32). The studies only covered a few exposure scenarios, including occupant exposure to resin pest strips and workers reentering treated warehouses. There were few, if any, adverse effects following most resin pest strip exposures. Only one headache was reported which may have been associated with dichlorvos exposure. Usually only plasma ChE inhibition was statistically significant with statistically significant RBC ChE inhibition occurring only rarely. However, interpretation of the study results is difficult because of methodological problems and utilization of outdated methods for measuring ChE activity. In addition, the studies only examined small numbers (less than 20) in any one test group.

(b) Poisoning incidents. Exposure to dichlorvos has resulted in poisoning incidents. Although the number of incidents is not large, it is sufficient to be of concern and can be viewed as confirmatory of the inadequate MOEs. Several sources are available indicating that exposure to dichlorvos has resulted in poisoning incidents. As part of the assessment for the dichlorvos Registration Standard, the Agency reviewed the Pesticide Incident Monitoring System (PIMS) data base covering a period from 1964 to 1980 (Ref. 33). Only 182 of the 598 dichlorvos incidents could be identified as involving products that contained dichlorvos as the sole active ingredient. A majority (147) of these 182 reports involve humans and domestic animals in the home environment, with 114 incidents resulting from ingestion and application of dichlorvos. One death was reported. Ingestion incidents usually involved children chewing flea collars and resin pest strips. Most of the application incidents involved situations where the existing label precautions were not followed. Of the remaining 416 incidents in which dichlorvos was cited in combination with other chemicals, there were 9 human fatalities reported. EPA's Incident Data System, in operation since June 1992, does not contain any human poisoning incidents attributed to dichlorvos exposure.

Case reports from the California Pesticide Illness Surveillance Program are available for dichlorvos from 1982 to

1990 (Ref. 34). A total of 78 poisoning incidents were attributed to dichlorvos exposure. Sixty were classified as systemic poisonings, 12 caused eye problems and the remaining 6 resulted in skin irritation. The majority of these incidents involved active ingredients in addition to dichlorvos. In addition, poisonings were attributed to both occupational and residential exposures.

Finally, the American Association of Poison Control Centers (AAPCC) reported that for the years 1985 - 1992 there were 21,006 exposures of all kinds for dichlorvos alone and 21,844 exposures for dichlorvos alone and in combination with other active ingredients (Refs. 35 and 36). Of the 21,006 exposures, 2,671 individuals were treated and released and 350 were hospitalized. There were 259 occupational cases involving dichlorvos alone and an additional 57 occupational cases involving dichlorvos in a mixture with another pesticide. Of the 259 cases, 99 workers were treated and released and 13 were hospitalized. Only one of the occupational cases was considered life-threatening, while 10 of the non-occupational cases were so categorized.

iii. Animal health and safety data. EPA reviewed 3 animal heath and safety data studies which examined the effect on dogs and cats of wearing registered cat and dog flea collar products. These studies provide strong evidence that dichlorvos, used in combination with other active ingredients, has a significant effect on reducing ChE activity in dogs. Although the ChE inhibition could result in part from another pesticide active ingredient, the Agency has no data to disprove that ChE depression is a result of dichlorvos exposure (Refs. 37-39).

In the first study, groups of 3 male and 3 female dogs per group served either as controls, or wore 1, 3, or 5 collars containing 9.3 percent dichlorvos and 4.2 percent chlorpyrifos. In the 1-collar group, 5 out of 6 dogs averaged RBC ChE inhibition (statistically significant) of 20 to 30 percent during the period day 3 through week 2. Plasma ChE inhibition was even greater, averaging 65.6 percent as compared to pre-test values during the perod day 3 through week 4 in 5 animals.

Another study was conducted in which 3 male and 3 female dogs were each assigned to a control group, a group wearing a collar containing 7.8 percent dichlorvos and 4.34 percent chlorpyrifos, a group wearing a collar containing 8.87 percent dichlorvos and 4.44 percent chlorpyrifos, and a group wearing an 8 percent chlorpyrifos collar. The mean percentage plasma ChE activity was significantly different from that of the control group among dogs wearing collars containing dichlorvos from day 7 through week 6. Differences in RBC ChE activity were not statistically significant. More specifically, in animals wearing the product containing 7.8 percent dichlorvos, plasma and RBC ChE activity were inhibited 49 percent and 19 percent as compared to pre-test values. This study demonstrates that plasma and RBC ChE inhibition also can occur from use of these products.

In the last study, ChE activity was measured in dogs over a 98–day period, during which time the dogs wore a placebo collar or 1, 3, or 5 collars containing a mixture of 7 percent dichlorvos and 9 percent propoxur. There was a considerable drop in plasma ChE activity in the first 7 days of exposure (in 1-collar dogs by 30 percent, in 3-collar dogs by 57 percent, and in 5-collar dogs by about 63 percent). In the 1-collar exposure group there was essentially complete plasma ChE recovery by day 56; however, in the 3 and 5-collar females there was still significant plasma ChE inhibition (35 and 43 percent, respectively) on day 98. There was no evidence of any RBC ChE inhibition in any group at any time during this study.

iv. Dose-response assessment. Results from acute, subchronic, and chronic toxicity studies have shown dichlorvos to be a potent inhibitor of plasma, RBC, and brain ChE. In most instances, inhibition of brain ChE occurred at similar doses as plasma and RBC ChE inhibition. Moreover, cholinergic signs were usually associated with actual measurements of ChE inhibition. Neurotoxicity data indicate a correlation between ChE inhibition and neuropathological effects. Overall, the various indicators of ChE inhibition (i.e., altered ChE activity in plasma, RBC, brain, neuropathological effects or cholinergic signs) are observed within a relatively narrow dose range. In addition, the effects indicative of ChE inhibition observed in laboratory studies are further validated by actual human poisonings accompanied by cholinergic signs.

Dose-response data for ChE inhibition and/or cholinergic signs are available for acute, subchronic, and chronic toxicity studies using rats, rabbits, dogs and hens as the test species. EPA selected the lowest NOELs from acute, subchronic, and chronic toxicity studies to calculate MOEs of exposure for individuals exposed to dichlorvos for varying durations of time. The NOELs are based on either brain ChE inhibition and/or cholinergic signs following administration of dichlorvos by the oral and inhalation routes of exposure. Neurotoxicity data following dermal administration of dichlorvos are not available.

(a) Acute/short-term exposure. EPA scientists believe that a NOEL of 0.5 mg/kg/day is most suitable for calculating MOEs of exposure for acute dietary and short-term occupational or residential (1 to 7 days) exposure scenarios. This NOEL is based on the acute neurotoxicity study in rats resulting in neurological and physiological changes observed shortly after dosing, including alterations in posture, mobility, and gait, reduced or absent forelimb/hindlimb grasp, increased time to first step, pupillary constriction, tremors, clonic convulsions, increased response time, catalepsy, and reduction in body temperature at 35 mg/kg/day. ChE activity was not measured in this study. There is some uncertainty with this acute NOEL because of the wide gap between dose levels (0, 0.5, 35, or 70 mg/kg/day). Since there are no intermediate doses between the no effect level of 0.5 mg/kg/day and the next level, 35 mg/kg/day, at which a variety of behavior changes were seen, it is possible that additional data might result in a slightly higher NOEL. However, Agency scientists do not believe that such a new acute NOEL would differ greatly from 0.5 mg/kg/day because short-term exposure data from other studies yielded similar results.

(b) Intermediate exposure. EPA selected a NOEL of 0.1 mg/kg/day for assessing intermediate occupational and residential exposure (1 week to several months) to dichlorvos. This NOEL was derived from examining several oral and inhalation toxicity studies. In the subchronic rat neurotoxicity study, administration of dichlorvos at 7.5 mg/kg/day inhibited plasma, RBC, and brain ChE activity, as well as producing cholinergic signs during the third week of dosing. Based on these findings, a NOEL was established at 0.1 mg/kg/day. The inhalation developmental toxicity study in rabbits demonstrated a NOEL of 0.14 mg/kg/day (converted from 0.25 μg/L) based on statistically significant plasma, RBC and brain ChE inhibition occurring at 0.71 mg/kg/day. A maternal toxicity NOEL of 0.1 mg/kg/day was demonstrated in the oral developmental toxicity study in rabbits, based on the results of the range-finding and definitive studies. In the range-finding study, statistically significant plasma and RBC ChE inhibition occurred at all doses except 0.1 mg/kg/day, while cholinergic signs occurred at 2.5 mg/kg/day and above. ChE inhibition was not measured in the definitive study, but 2

deaths (13 percent) occurred at 2.5 mg/kg/day. The developmental toxicity study results are supported by the 1 year dog study in which significant plasma and RBC ChE inhibition occurred as early as 2 weeks following administration of 1.0 and 3.0 mg/kg/day. In addition, plasma ChE inhibition ranged from 21 to 26 percent in the 0.1 mg/kg/day group at 2 weeks. These studies indicate that effects associated with ChE inhibition occur at levels slightly higher than 0.1 mg/kg/day. Therefore, EPA has determined that the study results support a NOEL of 0.1 mg/kg/day for calculating margins of exposure for intermediate exposure.

(c) Chronic/long-term exposure. The oral and inhalation toxicity studies that EPA has evaluated resulted in comparable NOELs for assessing chronic dietary and long-term occupational and/or residential exposure (substantial portion of a lifetime). The inhalation study in rats demonstrated a NOEL of 0.055 mg/kg/day (converted from 0.05 mg/m^3) based on statistically significant ChE inhibition in plasma, RBC, and brain at 0.48 mg/m^3. The oral study in dogs resulted in a NOEL of 0.05 mg/kg/day, based on statistically significant plasma, RBC, and brain ChE inhibition at 1.0 mg/kg/day. EPA rounded the inhalation NOEL to 0.05 mg/kg/day for ease in calculating MOEs. In addition, there is uncertainty associated with converting from mg/m^3 to mg/kg/day in the chronic inhalation study.

3. *Adverse liver effects.* The PD 1 also cited a concern for adverse liver effects resulting from exposure to dichlorvos. A 2–year dog feeding study indicated increased liver weight and enlargement of liver cells with a NOEL of 0.08 mg/kg/day. EPA recently reevaluated this study and downgraded its acceptability from minimum to invalid. The study was reclassified because the actual dose ingested by the animals cannot be confirmed, due to impurities and decomposition products in the test material.

In addition, the 1 year oral dog study cited above was reviewed for the purpose of evaluating the validity of the liver effect concern. No liver effects were reported after 1 year of treatment at higher doses than the doses in the invalidated 2–year study. Therefore, this endpoint is no longer of regulatory concern.

C. Exposure Analysis

1. *Dietary exposure*—i. Background. Dietary exposure to a pesticide depends on two components: the amount of pesticide residue on a commodity and how much of that commodity is consumed. In estimating dichlorvos residues on food, EPA relied on a variety of data for dichlorvos, including tolerance levels (the legal maximum residue) and field trial data (measured residues resulting from actual application of dichlorvos). In addition, these estimated residues can be further refined by taking into account the effects of processing and cooking on treated foods, and by estimating the percent of the crop that is treated.

The Agency currently uses food consumption values derived from a USDA survey to estimate dietary exposure to pesticides. The USDA conducted a nationwide survey (1977-1978) of the food consumption patterns of 30,770 individuals for 3 days. Based on this survey, EPA can estimate the dietary exposure and risk for the U.S. population and 22 subgroups of the total population using a computer-based tool called the Dietary Risk Evaluation System (DRES). DRES multiplies the average daily consumption values by residue information for each commodity to obtain the total dietary exposure. In the absence of data for residues of dichlorvos on crops and an estimate of the percent of the crop treated with a pesticide, EPA estimates exposure based on the Theoretical Maximum Residue Contribution (TMRC). The TMRC assumes residues on crops are present at tolerance levels (the maximum residue limit allowed by law) and 100 percent of the crop is treated. When EPA has additional data to refine the TMRC, based on residue data and estimates of percent of crop treated, the Agency uses this new information to calculate the Anticipated Residue Contribution (ARC). When available, the ARC is used instead of the TMRC in estimating residues.

Dietary exposure to dichlorvos residues may occur as a result of use on a variety of sites. These sites include greenhouse food crops, food or feed containers, bulk-stored, bagged or packaged nonperishable raw agricultural commodities (RACs) food, and bulk stored, bagged or packaged nonperishable processed commodities, commercial food processing plants, groceries, eating establishments, livestock (direct animal treatment), swine feed (as a dewormer), and food in homes where resin pest strips are located.

Tolerances and FARs exist for residues of dichlorvos in or on raw agricultural and processed products and on meat, milk, poultry and eggs. As noted in the Registration Standard, even though dichlorvos is registered for use in food handling establishments (including food processing, food manufacturing and eating establishments), there are no FARs for the related uses.

In estimating dietary exposure for the initiation of Special Review in 1988, the Agency did not have sufficient data on actual residue levels. Therefore, EPA's dietary exposure estimate at that time was based on the assumption that residues were present at tolerance levels (40 CFR 180.235). Residues were adjusted based on cooking data on small grains and on an estimate of percent of crop treated. At the time of the initiation of Special Review, EPA estimated that the average consumer in the U.S. population was exposed to 4.2×10^{-2} mg/kg/day of dichlorvos. This may have been an overestimate of chronic exposure because tolerance level residues were assumed. However, limited data available at that time suggested that some residues were at or above tolerance levels (nonperishable stored foods). In addition, exposure could have been underestimated because, in the absence of a FAR for food handling uses, the exposure estimate did not consider residues from food handling uses, or any degradation resulting from two related pesticides, naled and trichlorfon.

Amvac recently notified the Agency (Ref. 40) that it is not supporting the reregistration of greenhouse food and nonfood uses and that it requests voluntary deletion of those uses. Therefore, some exposure may be eliminated as a result of these voluntary deletions, or due to cancellation of uses related to the revocation of the FAR for packaged or bagged nonperishable processed food. However, since these actions have not occurred, EPA will continue to consider these residues for this proposed determination.

ii. Naled and trichlorfon. Naled and trichlorfon degrade to dichlorvos through plant metabolism. Three factors will significantly affect dietary exposure to dichlorvos from registered uses of naled and trichlorfon; these include, the preharvest interval (PHI), the condition and length of storage, and cooking and processing. Naled is metabolized to dichlorvos by plants. Plant metabolism studies show that dichlorvos residues are formed 1 to 3 days after treatment with naled and trichlorfon; however, dichlorvos residues are less than the limit of detection (0.01 to 0.05 ppm) 7 days after treatment. In general, registered uses of naled have PHIs of less than 7 days, while trichlorfon registrations have PHIs greater than 7 days. Because of the short PHIs for naled products, measurable residues of dichlorvos may be present in the U.S. diet from naled treated food. EPA does not expect measurable residues from

trichlorfon because of the longer PHIs. As a result, the dietary exposure assessment for dichlorvos includes residues of dichlorvos resulting from the application of naled but not from trichlorfon. Neither naled or trichlorfon, themselves, have carcinogenic potential in humans as concluded by EPA (Refs. 41 and 42)

iii. Data available for determining the ARC. Possible sources of data to estimate the levels of residues to which the public is exposed, when consuming treated commodities include: Tolerance levels, controlled field trials, Food and Drug Administration (FDA) surveillance and compliance monitoring data, FDA Total Diet Study data (market basket survey based on a random sampling of residues on food in grocery stores), USDA pesticide data program, and USDA/FSIS (Food Safety Inspection Service) livestock monitoring data. The estimated levels of residues can then be adjusted for the effects of processing using processing studies, including commercial processing studies, washing studies, cooking studies, and residue degradation studies. Of these sources, the Agency relied on tolerance levels and field trial data (adjusted for the effects of processing and cooking) to estimate dietary exposure to dichlorvos. For a variety of reasons, the other sources did not provide useful data (Ref. 43).

(a) Tolerance levels. Tolerance levels are used for an initial dietary exposure analysis. Use of tolerance levels typically overestimate chronic exposure because tolerance levels are set at a level that is not likely to be exceeded when the pesticide is used according to the label. Tolerance levels are also used in dietary exposure assessments when no other appropriate data are available. In the case of dichlorvos, no other data are available which reflect currently registered uses on cucumber, lettuce, tomato, and radish, and, therefore, tolerance levels are used here to estimate residues on these crops.

(b) Field trials. Data from controlled field trials which reflect currently registered uses are not available for most agricultural uses of dichlorvos, since these uses are not being supported for reregistration. Field trial data are available for mushrooms and figs, and data from direct dermal treatments to cattle and poultry are discussed in the dichlorvos Registration Standard. Field trial data are also available for use on packaged or bagged food, use in food manufacturing and processing facilities, and for secondary residues in livestock commodities. EPA is including residue estimates for figs (raw and dried), even though these tolerances were revoked, because figs may be located in warehouses or areas where similar packaged, bagged, or bulk commodities are treated.

(c) Processing and cooking studies. Residues for raw commodities can be modified by processing factors to account for changes during commercial or other processing and cooking. Processing, cooking and decline (half-life) studies were available for cocoa beans, dry pinto beans, tomato juice, ground roasted coffee beans, raw hamburger meat, raw eggs, and raw whole milk. The resulting cooking factors were used to reduce the Agency's estimate of residues for these commodities and were translated to other commodities based on similarity of cooking time and temperature. Additional cooking studies were available and discussed in the Residue Chemistry Chapter of the Registration Standard. Half-lives of dichlorvos in various commodities ranged from 0 to over 1,000 hours. The reduction of dichlorvos in cooking appeared to be related to the length of time and temperature used in cooking. Residues were adjusted based on these cooking factors to obtain the ARC.

(d) Anticipated residues for dichlorvos—(*1*) Raw commodities. The following registered uses are not being supported for reregistration and the Agency does not have residue data reflecting current uses: tomatoes, cucumbers, lettuce, and radishes. Therefore, current tolerance levels are assumed in the exposure assessment. Amvac has requested voluntary deletion of these uses from their labels; however, because the deletion of these uses is not final, EPA is including these commodities in the exposure assessment. Anticipated residues for raw commodities as bulk, packaged, or bagged food are discussed below.

(*2*) Meat, milk, poultry and eggs. Residues in livestock tissues, including milk and eggs, may result from consumption of dichlorvos treated livestock feeds, direct dermal treatments, or from use as a drug in swine. Livestock metabolism studies done at exaggerated rates in ruminants and poultry have demonstrated that oral ingestion of dichlorvos by cattle and poultry will not result in detectable residues. This conclusion can be extended to the drug use of dichlorvos in swine. Secondary residues in livestock from consumption of treated feed are expected to be so low that EPA is estimating these residues as zero. Data reflecting direct livestock treatments are discussed in the Residue Chemistry Chapter of the Dichlorvos Registration Standard. Data from direct dermal studies indicate that detectable residues are not expected, except in skin. Residues are non-detectable (<0.01 ppm) in cattle tissue and milk, and non-detectable (<0.05 ppm) in poultry tissues and eggs. The exposure assessment uses one-half the limit of detection in both cases. In the absence of direct dermal studies for swine, the Agency estimated the residue on swine to be 0.08 ppm. This estimate was based on a study in poultry that approximated the rate for direct dermal swine treatment.

(*3*) Bulk stored, packaged or bagged commodities, food and feed handling uses. The ARCs used in the exposure assessment for packaged, bagged or bulk stored food are based on studies submitted by Amvac (Ref. 44). Residue data were submitted for many commodities. For those commodities where data were not submitted, EPA translated residue data from similar commodities. For example, data on dry beans are translated to other legumes; data on wheat flour are translated to all flours and meals, etc. In addition, residue data were provided for corn and oats at various points during processing, and for flour, sugar, dried milk, dried eggs, shortening, and baking mix from a treated manufacturing facility. Bulk stored commodities are assumed to be uncovered when treated. Although pesticide labels state that bulk or unpackaged foods should be covered or removed before spraying, it is not possible to assess the effect of covering food since the type of material used in the cover is not specified and the manner in which food is covered would vary considerable. Therefore, food is assumed to be uncovered. Since the proportion of commodities stored in bulk vs. packaged/bagged is unknown, the ARCs are based on an average of the residues found in bulk and packaged/bagged food for any particular commodity.

The FAR in 40 CFR 185.1900 for packaged or bagged nonperishable processed foods and the tolerance in 40 CFR 180.235 for nonperishable packaged, bagged or bulk raw food do not refer to specific commodities. Therefore, EPA has developed a list of commodities likely to be treated with dichlorvos that are covered by tolerances and/or FARs. Because these tolerances and FARs were established to cover residues resulting from use at different sites (for example, wheat could be treated in its raw form in a silo, later as flour, during processing into cake mixes, and finally as a stored packaged commodity), cancellation of any one of the site-specific uses does not necessarily eliminate the risk of a

commodity from dichlorvos treatment. EPA did not combine the residues from different sites in creating the ARCs, although the cumulative residues from treating a commodity at different sites are considered in the estimation of percent of crop treated (see paragraph (e) below).

Dichlorvos is registered for use in a variety of food handling establishments, including: food service establishments (such as restaurants and other locations where food is served and grocery stores); manufacturing establishments (such as candy plants, spaghetti and macaroni plants, bottling plants, and pizza plants); and processing establishments (such as meat, poultry and seafood packing plants, dairies and dairy product plants, frozen fresh food plants and grain mills). EPA has data for estimating residues in manufacturing establishments and processing establishments; however, there are no data for estimating residues in eating and serving areas of food service establishments. EPA did not include residues from this use in its exposure assessment. Therefore, to the extent that dichlorvos is used in food service establishments, the Agency's exposure assessment is an underestimate of potential dichlorvos dietary exposure.

(*4*) Use of naled. All naled tolerances in 40 CFR 180.215 were evaluated as a potential source of dichlorvos residues. Anticipated residues are based on either tolerance levels or field trials. Naled and dichlorvos residue estimates were reduced when data were available for the effects of washing, cooking, and processing. In addition, wide area application of naled in mosquito and fly control use could result in residues potentially on all crops in the Agency's Dietary Risk Evaluation System. Therefore, EPA included all these crops in its estimate of anticipated dichlorvos residues. Although it is possible that dichlorvos residues could occur on any raw agricultural commodity from this use of naled, it is unlikely that residues would be found on all commodities. As a result, this inclusion of residues from all raw crops presents a possible source of overestimation of dietary exposure. As discussed earlier, EPA does not expect measurable residues from the use of trichlorfon because of the longer PHI for trichlorfon than for naled.

(*5*). Percent of crop treated information. In conducting a chronic risk assessment, EPA refines its estimate of dietary exposure based on percent of crop treated when such information is available. In the absence of this information, EPA assumes that 100 percent of the crop is treated. Where a range of percent crop treated values are supplied for this analysis, the upper end of that range is assumed (Refs. 45-47).

(*i*) Dichlorvos. Although no quantitative estimates of percent of crop treated were given for the agricultural sites of dichlorvos (radishes, mushrooms, cucumbers, lettuce, and tomatoes), the Agency assumed that less than one percent of these crops has dichlorvos residues, because EPA's proprietary data indicates little or no use. EPA earlier assumed, in the proposed revocation of the FAR for residues of dichlorvos on packaged or bagged nonperishable processed food, that the percent of crop treated estimate of 7.5 percent for food processing plants should be applied to all sites, and therefore, to all raw and processed non-perishable packaged or packaged food. The present analysis assumes that the percent of sites treated at various points in the processing and distribution channels should be added rather than averaged, because, as discussed earlier, cancellation of any one of the site-specific uses does not necessarily eliminate the risk of a commodity from dichlorvos treatment. EPA now estimates that 20 percent of the crop is treated based on the sum of percent of crop treated estimates for bulk storage, processing plants, and warehouses.

(*ii*) Naled. Naled is used for mosquito and fly abatement in municipalities, residential areas, swamps, tidal marshes, and woodlands. Naled is also registered for controlling pests on several specific agricultural sites. Application of wide area mosquito control by air can result in drift or direct treatment to small crop areas or margins of large fields. Because the mosquito and fly abatement use is applied in agricultural settings without regard to a specific crop, EPA has no way of eliminating any crops from its anticipated residue estimate. Therefore, EPA is assuming that one percent of all agricultural crops may potentially have dichlorvos residues resulting from mosquito and fly abatement use. For certain crops which are grown in water-filled areas (such as sugarcane) this may be an underestimate. However, this one percent is considered an overestimate of percent of crop treated across all commodities. For registered uses of naled on specific crops, EPA used that specific percent of crop treated data instead.

2. *Occupational and residential exposure*. Dichlorvos is used in a wide variety of situations, involving different application methods and equipment; at home, at work and in public areas. Individuals are exposed to dichlorvos as professional applicators, and as reentry workers. Residents are exposed from applying dichlorvos themselves at home and from post application exposure. Individuals can also receive post-application exposure at work or in public places. Pet flea collars may pose a risk for both the pet and people who come in contact with the dog or cat. Depending on the method of application or use, exposure to dichlorvos can occur by either the dermal or inhalation route or both. Because of the wide variety of uses for dichlorvos it is difficult to estimate exposure for every possible situation. Therefore, the purpose of this assessment is to estimate exposure in those situations thought to have the greatest exposure and potential for the greatest risks. The Agency would particularly like comments regarding any uses with a significant exposure scenario not described in this Notice.

EPA completed a series of exposure assessments in August 1987 for the Registration Standard and PD 1. Many of the exposure assessments were based on limited data. Since that time, additional exposure data have been submitted to the Agency. These data have been evaluated and EPA has determined that revisions to the original assessments are appropriate. Based on this analysis, the Agency has revised exposure estimates for the following uses: Crack and crevice application; application to greenhouses, mushroom houses, dairy barns and milk rooms. In addition, new data are available which allow the Agency to estimate exposure from use of household aerosol and total release fogger products. New exposure estimates have been developed for warehouse treatment, and use on dairy cattle, buses, and commercial vehicles. EPA used a variety of data for estimating occupational and residential exposures. These data included studies which measured dichlorvos following the use of a registered pesticide, surrogate studies involving other chemicals which used the same or similar application methods that would be used for dichlorvos uses, and in the absence of these two data sources, the Agency used its best professional judgment in estimating exposure. EPA's exposure estimates, including assumptions, are presented in Table 1 in Unit II.C.2. of this document (Refs. 48- 51).

The revised exposure estimate for crack and crevice treatment by pest control operators (PCOs) considered data that were not available at the time of the original assessment. Under most conditions, the Agency assumed that professional applicators would wear a long sleeve shirt, long pants, and gloves.

Data are also available to revise exposure estimates for application to greenhouses, mushroom houses, and

dairy barns (milk rooms). Because a variety of application equipment could be used to treat these sites, depending on product formulation, the specific pest problem and personal preference of the applicator, EPA evaluated several studies, each using a variety of application equipment. Since these studies varied in design, it was not possible to pool the data into one large data set. Therefore, EPA calculated exposures separately for each study design, using correction factors for protective clothing where necessary. Normal work clothing (i.e., long sleeve shirt and long pants) was assumed to offer 50 percent protection, while gloves, coveralls and shoes were assumed to decrease exposure 90 percent. This approach resulted in a range of estimated exposures for each of the three sites. Table 1 in Unit II.C.2. of this document summarizes these data.

The potential exposure of applicators using household aerosol products was not directly addressed in earlier Agency assessments. Since that time, EPA has received a study monitoring the exposure of individuals during application of a one percent propoxur aerosol product. This study can be used as a surrogate study for aerosol products containing dichlorvos. EPA believes that application of one entire can of pressurized aerosol represents a reasonable exposure estimate for acute exposure scenarios. This may be a conservative estimate in that not every resident will use an entire can at one time; however, it is reasonable to assume that some individuals may choose to apply an entire can. Exposure estimates were calculated for four different clothing scenarios: (1) Long sleeve shirt, long pants, and shoes; (2) short sleeve shirt, long pants, and shoes; (3) short sleeve shirt, shorts, and shoes; and (4) and minimal clothing consisting of shorts and shoes only. EPA is using a conservative clothing assumption of only shorts and shoes because insects may present the greatest nuisance in the summer when residents are likely to wear the least amount of clothing.

EPA has also estimated exposures for individuals occupying or reentering residences following treatment of rooms with a total release fogger. These exposure estimates are also applicable to individuals reentering homes following crack and crevice treatment and aerosol spray application. The exposure estimates are based on a study that measured potential exposure by monitoring urinary amounts of dimethyl phosphate (DMP), a metabolite of dichlorvos, and by using whole body dosimeters consisting of cotton shirts, tights, gloves, socks and underpants. Because it appears that dichlorvos passed through the dosimeters, use of the dosimeter data alone would underestimate exposure. Therefore, EPA calculated total exposure by adding the biomonitoring component and the amount trapped by the whole body dosimeters. This is a conservative approach because it assumes that the entire amount of dichlorvos trapped in the clothing could serve as a pool for subsequent absorption. It is likely that some loss of dichlorvos from the clothing would occur and, therefore, would not be available for absorption. When biological monitoring alone is performed, it is not possible to separate the dermal and respiratory components of exposure. For this reason and because the study addresses a homeowner/resident scenario where protective clothing and respiratory protection do not apply, EPA has not separated these components but rather addressed the total exposure of the volunteers without regard to route. In addition, EPA is unable to estimate daily exposure values because biomonitoring data were collected over a 2–day period in this study. Rather, EPA estimated total exposure to individuals performing activities at various intervals following treatment on 2 consecutive days.

TABLE 1.—SUMMARY OF DICHLORVOS NON-DIETARY RISKS

Uses	Notes	Exposure (mg/kg/day)		Exposure Pattern[1]	Margin of Exposure (Cholinesterase Inhibition)
		Dermal	Inhalation		
Domestic Dwellings (application)	2				
Pressurized aerosol	3	0.097	3.3×10^{-7}	Short-term	47
Crack and crevice treatment	4	0.018	2.3×10^{-4}	Long-term	23
Domestic Dwellings (post-application)		No data			
Total release fogger	5		0.03	Short-term	17
Pressurized aerosol	6		0.03	Short-term	17
Crack and crevice treatment	7		0.03	Long-term	2
Resin pest strips	8		2.5×10^{-3}	Long-term	20
Pet flea collars	9		2.1×10^{-4}	Long-term	240
Occupational Exposure	10				
Crack & crevice treatment in homes	11	0.078	negligible	Long-term	6
Mushroom House	12				

TABLE 1.—SUMMARY OF DICHLORVOS NON-DIETARY RISKS—Continued

Uses	Notes	Exposure (mg/kg/day)		Exposure Pattern[1]	Margin of Exposure (Cholinesterase Inhibition)
		Dermal	Inhalation		
Applicator		4.0×10^{-5} to 0.74	1.8×10^{-5} to 6.7×10^{-4}	Intermediate	Majority of scenarios have MOEs less than 50, and some are less than 10
Reentry		ND	1.5×10^{-2}	Short-term	21
Greenhouse	13				
Applicator		2.6×10^{-5} to 0.48	4.4×10^{-4} to ND	Short-term	Majority of scenarios have MOEs less than 100, and 30% of scenarios have MOEs less than 50
Reentry		2.7×10^{-4}	0.18	Short-term	2.8
Domestic food/nonfood animals (non-poultry)	14	0.15	No data	Intermediate	6.1
Domestic food/nonfood animals (poultry)	15	< non-poultry	No data	Intermediate	> 100
Domestic animal premises (food and non-food) (Dairy barns)	16				
Applicator		1.2×10^{-5} to 0.03	ND - 2.0×10^{-4}	Short-term	> 100
Reentry		No data	No data	Short-term	> 100
Feedlots	17	< greenhouse	< greenhouse	Short-term	> 100
Manure	18	< greenhouse	< greenhouse	Short-term	> 100
Tobacco warehouse	19				
Applicator - sprinkling with water can		0.2	ND	Long-term	2
Mixer-loader		1.4×10^{-5}	ND	Long-term	32,500
Warehouse worker (reentry)		No data	0.20	Long-term	0.3
Ornamental lawns, turf and plants	20				
Applicator		2.6×10^{-5} to 0.48	4.4×10^{-4} — ND	Short-term	32 Similar to power sprayer in green house
Warehouse treatment (affects nonperishable bulk, packaged and bagged raw and processed commodities)	21				
Application		0.1	0.002	Short-term	38

TABLE 1.—SUMMARY OF DICHLORVOS NON-DIETARY RISKS—Continued

Uses	Notes	Exposure (mg/kg/day)		Exposure Pattern[1]	Margin of Exposure (Cholinesterase Inhibition)
		Dermal	Inhalation		
Reentry		2.7×10^{-4}	0.18	Short-term	2.8
Kennels Applicator	22	similar to dairy barn	similar to dairy barn	Short-term	> 100
Insect traps	23	negligible	negligible	Short-term	negligible risk
Garbage dumps	24	< greenhouse	< greenhouse	Short-term	> 81
Commercial, institutional and industrial areas Application Reentry	25	 0.1 2.7×10^{-4}	 0.002 0.18	 Short-term Short-term	 38 2.8
Commercial transportation vehicles Airplanes (disinsection of aircraft) Passenger - post-application Applicator	26	 No data No data	 3.7×10^{-3} 3.7×10^{-3}	 Short-term Long-term	 135 14
Buses - passenger	27		9.2×10^{-3}	Short-term	55
Truck, shipholds, rail cars Applicator Reentry	28	 < warehouse negligible	 < warehouse 2.45×10^{-2}	 Short-term Short-term	 > warehouse 20

ND--Not Detectable

Notes: The following notes define the assumptions used in calculating the margins of exposure.

1. Short-term MOEs based on NOEL of 0.5 mg/kg/day; Intermediate MOEs based on NOEL of 0.1 mg/kg/day; Long-term MOEs based on NOEL of 0.05 mg/kg/day.

2. An average resident weighs 70 kg and has a respiratory volume of 1.7 m^3 per hour. No protective clothing is assumed.

3. Resident use of pressurized aerosol product is based on application of an entire one percent 16 ounce can of pressurized aerosol. EPA estimated the risk to residents for different clothing scenarios. The MOE of 47 assumes the resident is wearing only shorts and shoes. Pressurized aerosol products containing dichlorvos do not have any clothing requirements, therefore EPA is assuming that dichlorvos is applied during hot weather when an individual will be wearing the least amount of clothing.

4. Dichlorvos is applied once per week for 44 weeks while wearing no protective clothing.

5. Assumes less than 24 days of exposure per year and less than 2 days/month. The value 0.03 reported in the table includes both dermal and inhalation, since it is based on biomonitoring data (blood samples) and represents the dose to the individual rather than exposure. All other dermal exposure values in the table must be adjusted by the dermal absorption factor of 0.11 to arive at the dose.

6. Same as for fogger.

7. Same as for fogger.

8. Assumes 365 days of exposure per year, 24 hours per day.

9. Assumes 365 days of exposure per year, 24 hours per day.

10. An average worker weighs 70 kg and has a respiratory volume of 1.7 m^3 per hour. For mushroom houses, dairy barns, and greenhouses it is difficult to provide a single exposure estimate because of the variety of possible application equipment and differences in how studies were conducted. Therefore, a variety of scenarios are presented for these three uses. At a minimum, the following protective clothing was used in the exposure scenarios: gloves, long-sleeve shirt, long pants.

11. A 0.5% solution of dichlorvos is applied using a hand held low pressure sprayer. It is assumed that dichlorvos is applied by PCO 10 times per day 1 day a week for 44 weeks. An average commercial applicator wears coveralls, chemical resistant gloves, and shoes. A respirator is not worn.

12. An average mushroom house has a volume of 30,000 ft^3. Dichlorvos is applied at a rate of 3.0 grams of active ingredient per 1000 ft^3 or 30 grams per treatment; 16 days per year, 10 houses per day; 4 minutes per house or 40 minutes per day. Protective clothing was slightly different for each application method. For reentry exposure, EPA assumed that a worker reenters a ventilated mushroom house 24 hours after treatment and is exposed for 8 hours. Dermal exposure is assumed to be negligible compared to respiratory exposure.

13. A typical greenhouse operation consists of seven greenhouses, each with a volume of 85,000 ft^3. All seven greenhouses are treated in one day. There are a maximum of three applications per crop and three crops are produced per year. Dichlorvos is applied at the rate of 1.4 grams of active ingredient per 1000 ft^3. The total time spent applying the insecticide is 26.25 minutes per day or 3.94 hours per year. The exposure value assumes that, at a minimum, a worker wears a long sleeve shirt, impervious gloves. In the absence of reentry data for a greenhouse, EPA is assuming that reentry exposure is similar to that of a warehouse.

14. Worker exposure from direct application to animals is based on dairy cattle treatment. EPA does not believe that direct application with a handheld sprayer is used primary method of application. However, since several registered products provide guidance on use with a handheld sprayer, the exposure and risk are estimated here for that application method. A one percent solution of dichlorvos is applied with a handheld sprayer. An average herd of dairy cattle consists of 65 head, each requiring 24 seconds to spray, two times per day during treatment. Fly control is required from May to October with application

occurring weekly during this time (26 times per year). Personal protective equipment consisting of impervious gloves (90 percent protection), long sleeve shirt and long pants (50 percent) protection are worn.

15. Data for cattle cannot be extrapolated to poultry, because of the different application method and less frequent applications for poultry. As a result, exposure from applying dichlorvos to poultry is expected to be much lower than for cattle.

16. An average dairy barn has the dimensions 30 ft x 100 ft x 9 ft (total area covered is 4340 ft^2). Dichlorvos is applied at two week intervals for 22 weeks, one barn per day. A 1.0 percent solution of dichlorvos is applied using a low pressure hand sprayer at a rate of 3.4 gallons per hour. Daily exposure time is 0.20 hours. A worker wears a long sleeve shirt, long trousers, shoes and impervious gloves at a minimum. Gloves offer 90 percent protection to the hands and the other garments 50 percent protection. Coveralls are assumed to offer 90 percent protection.

17. Feedlots include stockyards, corrals, holding pens and other areas where groups of animals are contained. This application method would probably be used for controlling insects on cattle. EPA assumes that some type of power sprayer capable of treating a large number of animals in a short time is probably used. A short application time period in an outdoor or partially enclosed area would minimize exposure to less than that of a greenhouse.

18. MOE is expected to be greater than 100 for manure use. Application equipment may be similar to those used in a greenhouse; however, the application time would probably be less and the treated area would be well ventilated - either outdoors or in a partially enclosed area.

19. Tobacco warehouse mixer/loader/applicator exposure is expected occur twice a week for 27 weeks, totaling 54 days of exposure. Warehouse reentry workers are expected to be exposed six days a week for 27 weeks per year.

20. Use on ornamental lawns, turf and plants are expected to have an exposure pattern similar to a greenhouse sprayer.

21. Dichlorvos can be applied to warehouses manually using foggers or with wall-mounted automatic foggers. Exposure to mixer/loaders through automatic application is expected to be negligible; however, there would still be reentry exposure. In estimating reentry exposure, EPA assumed six hours elapsed before reentry is allowed, as required on labels; and that workers spend eight hours per day in the treated area for the next three days. In estimating exposure from manual application, EPA assumed that an average warehouse has a volume of two million ft^3; dichlorvos is applied at the rate of 2.0 grams active ingredient per 1000 ft^3 over a period of 125 minutes per application. On average, dichlorvos is applied 12 times per year. Protective clothing consisted of impervious gloves, an apron, coveralls, boots, hood, goggles and a respirator during application.

22. Exposure in a kennel is believed to be similar to a dairy barn.

23. Exposure is believed to be negligible since the pesticide is in the form of an impregnated strip and the traps are placed in outdoor areas (such as forests) where there is no human exposure.

24. Exposure at a garbage dump is believed to be less than greenhouse exposure.

25. Exposure is believed to be similar to warehouse exposure.

26. Aircraft personnel are exposed to dichlorvos 30 minutes once per week, 52 times per year. No protective clothing is worn, representing a chronic exposure scenario. Passenger exposure is an acute scenario.

27. Passengers are exposed to airborne dichlorvos for four hours in buses following two hours aeration. Passenger respiratory volume is assumed to be 0.44 m^3/hour which is less than for workers because passengers are at rest.

28. EPA is assuming that exposure from application should be less than that for warehouses because of the smaller area to treat - therefore less exposure time. However, because a short term exposure scenario is involved, EPA is concerned about the potential risks from any type of hand application, assuming no respiratory protection. For reentry, the MOE of 20 is based on 8 hours of exposure after a 12–hour reentry period. Even a 24 hour reentry peroiod results in an MOE of 60.

D. Risk Characterization

1. *Chronic dietary*. This section summarizes chronic risk estimates from dietary exposure to dichlorvos, including risks due to direct application of dichlorvos and dichlorvos which occurs as a metabolite from the use of naled. In initiating the Special Review in 1988, EPA estimated the upper bound dietary cancer risk from dichlorvos application alone to be 8.4 x 10^{-5} or in the range of 10^{-4}, for the general U.S. population. EPA believed this to be an overestimate because it was based on a number of conservative assumptions. The Agency is now able to provide a more realistic dietary risk estimate based on field trial data, processing and cooking data, and refinements in percent of crop treated data (Refs. 52 and 53).

i. Noncancer. The Agency estimates chronic dietary risks for noncancer endpoints by comparing dietary exposure to the Reference Dose (RfD). The RfD is an estimate of the daily oral exposure to humans over a lifetime that is not expected to result in adverse health effects. The RfD is based on the determination of a critical effect from a review of all toxicity data and a judgment of uncertainty. In the case of dichlorvos, the RfD is 0.0005 mg/kg body weight/day, based on a NOEL of 0.05 mg/kg body weight/day and an uncertainty factor of 100 to account for extrapolation from animal data to humans and variability in the human population. The NOEL, was taken from a 1 year feeding study in dogs in which plasma and red blood cell ChE inhibition (ChE) were the effects observed in males and females; in addition, brain ChE inhibition was observed in males (Ref. 54).

Using anticipated residues and percent of crop treated data, EPA estimated the exposure from registered uses of dichlorvos to be 0.000054 mg/kg body weight/day, which represents 11 percent of the RfD for the general U.S. population. EPA estimates that the ARC to the most highly exposed population subgroup, non-nursing infants under 1 year, is 0.000143 mg/kg body weight/day, or 29 percent of the RfD. The ARC for the U.S. population from dichlorvos derived from registered uses of naled is 0.000016 mg/kg body weight/day or 3 percent of the RfD. EPA estimates that the ARC to the most highly exposed population subgroup, ''non-nursing infants under 1 year,'' is 0.000057 mg/kg body weight/day, or 11 percent of the RfD. EPA concludes that the risk from ChE inhibition due to chronic dietary exposure is minimal and not of concern.

The Agency does not have a concern for cholinesterase inhibition from DDVP use on foods at this time. This conclusion is based on the dietary risk assessment for DDVP alone. If exposure from other cholinesterase inhibitors, either on the same or different foods in addition to DDVP were considered, a cumulative exposure may trigger a risk concern. The Agency currently has no methodology for assessing cumulative exposure from cholinesterase inhibitors via ingestion of treated foods. However, the Agency plans to pursue options towards this end in the coming years and at that time will solicit public input on possible methodologies.

ii. Cancer. In estimating the upper bound cancer risk, chronic dietary exposure is multiplied by the cancer potency of the chemical. This analysis uses the upper bound cancer potency factor (or Q_1*) for dichlorvos of 1.22 x 10^{-1} $(mg/kg/day)^{-1}$ and assumes that an individual is exposed over a 70–year lifetime. Based on these assumptions, the estimated upper-bound excess individual lifetime cancer risk from direct application of dichlorvos is 4.4 x 10^{-6} and from naled-derived dichlorvos it is 7.2 x 10^{-7} for a total of 5.1 x 10^{-6} (see Table 2 of this paragraph). At a future date, EPA will issue a Reregistration Eligibility Document for naled which provides further analysis of naled-derived dichlorvos. The major source of estimated risk is dichlorvos residues from use on packaged, bagged or bulk nonperishable processed or raw food (3.4 x 10^{-6}). The estimated risk from the three individual tolerances and FAR (bulk raw, packaged or bagged raw,

and packaged or bagged processed) cannot be separated because, as discussed earlier, a single commodity may be treated more than once at different stages of production. EPA has published a final revocation notice for the FAR for residues of dichlorvos on packaged or bagged nonperishable processed food. If this revocation becomes effective and the related uses are canceled under FIFRA, this source of dietary risk will be eliminated.

TABLE 2.—UPPER BOUND CANCER RISK ESTIMATES FROM USE OF DICHLORVOS

Tolerance Expression	Upper Bound Cancer Risk
Use of Dichlorvos	
Packaged or bagged, non-perishable processed food and RACs (including bulk stored, regardless of fat content)	3.4×10^{-6}
Milk	6.2×10^{-7}
Eggs	7.1×10^{-8}
Red Meat	1.1×10^{-7}
Poultry	3.7×10^{-8}
Agricultural uses	2.1×10^{-7}
Lettuce	1.6×10^{-7}
Cucumbers	2.6×10^{-8}
Tomatoes	1.4×10^{-8}
Mushrooms	2.6×10^{-9}
Radishes	9.8×10^{-10}
Naled derived dichlorvos	7.2×10^{-7}
Total	5.1×10^{-6}

2. *Occupational and residential risks—i. Carcinogenicity*. The PD 1 in 1988 estimated risks from cancer to pesticide workers and residents based on dermal and inhalation exposure. Since that time, as discussed earlier in this unit, EPA has decided that it is no longer appropriate to quantify cancer risk for the inhalation and dermal routes, as discussed above in Unit II. Therefore, cancer risks for workers and residents by the inhalation and dermal routes are no longer a concern for this preliminary determination.

ii. ChE inhibition. The duration and frequency of exposure vary considerably for the numerous uses of dichlorvos. MOEs are based upon comparison of exposure estimates against NOELs of 0.5 mg/kg/day for short-term, 0.1 mg/kg/day for intermediate, and 0.05 mg/kg/day for long-term exposure scenarios. The NOELs are based on brain ChE and/or cholinergic signs, and were derived from toxicological studies by the oral route; however, dermal exposure is an important route of occupational/residential exposure. Therefore, the Agency's oral exposure estimates are adjusted for the dermal absorption of dichlorvos (factor of 0.11), to account for the route-to-route extrapolation.

For most uses in Table 1 of Unit II.C.2. of this document, a single exposure estimate and corresponding MOE are given. However, this was not possible for mushroom houses, greenhouses, and dairy barns because of the number of potential application methods and the inability to combine the various studies into one data set. The Agency does not believe there are any naled-derived dichlorvos risks resulting from occupational/residential exposure because a tank mix study showed that naled did not readily degrade to dichlorvos under actual use conditions. This is consistent with the finding that dichlorvos results from plants metabolizing naled, as discussed above.

MOEs are used by EPA as an indication of the level of risk from ChE inhibition. EPA is generally concerned about exposures to humans where the MOEs are less than 100, since they may not provide an adequate MOE after accounting for uncertainty (i.e, extrapolation from animals to humans and variability in the human population). MOEs are less than the uncertainty factor of 100 for the majority of sites examined in this assessment, and some are less than 10. MOEs fall below 100 for both the applicator of dichlorvos and for individuals living or working in treated areas (Ref. 55).

The occupational and residential risk assessment contains the following uncertainties that could result in an underestimate or overestimate of the true risk: (1) In the absence of actual dermal toxicity studies, toxicity by the dermal and oral routes were assumed to be comparable after adjusting for differences in absorption, (2) subchronic and chronic inhalation data are available, and EPA assumed that toxicity by the oral and inhalation routes are comparable, (3) the NOEL used to calculate short-term MOEs is based on cholinergic signs, (4) the exposure parameters are dated and may have changed for some scenarios, (5) in many cases surrogate exposure data were used for estimating occupational and residential exposure, and in the absence of such data, the Agency made assumptions that a particular exposure should not exceed that of a scenario where surrogate or actual data existed, and (6) MOE estimates may vary significantly depending on the method of application and protective clothing assumptions.

There are additional uncertainties regarding potential risks to children exposed to dichlorvos from residential uses, including variability in activity patterns, the extent of non-dietary oral ingestion, due to hand object-to-mouth activity, respiratory rate and tidal volume, surface area to volume ratio, dermal absorption, and toxicological susceptibility. Consideration of children's risk could possibly have resulted in lower MOEs. However, the Agency believes that the proposed actions will nonetheless serve to adequately protect children from residential exposure. The Agency is currently conducting research to provide refinements to assess children's exposure, and is working to update our guidelines for household and work related exposures.

3. *Analysis of comments on the PD 1*. The Agency received comments relating to risks discussed in the PD 1. Rebuttal comments and complete Agency responses are on file in the dichlorvos Public Docket. The following is a summary of the major comments, and the Agency's responses.

Comment. Amvac Chemical Corporation argued that the ''weight-of-the evidence'' from animal studies is limited or inadequate to assess human cancer risk, and that the Group B2 classification is not appropriate.

Agency Response. This comment is moot since dichlorvos was reclassified from a B2 to a C carcinogen, as explained above.

Comment. With regard to the pancreatic tumors seen in F344 rats, ''Since there are no pharmacokinetic or physiological reasons to expect females to be unique in their responsiveness to dichlorvos, the absence of an effect in females weakens the significance of the effect increase in males.''

Agency Response. The pancreatic acinar adenomas were eliminated from consideration in the fourth cancer peer review.

Comment. With regard to the dichlorvos swine feeding study, the registrant states that the ''histopathological results are of value for the assessment of the carcinogenicity of dichlorvos in a third species.''

Agency Response. The Agency does not believe that this study would be

adequate as an oncogenicity study in a third species because of the limited duration of the study and the limited histopathology apparently conducted.

Comment. With regard to the dichlorvos dog feeding study (2–year), the registrant stated that ''[t]he study showed no suggestion of carcinogenic effects of DDVP in dogs.''

Agency Response. The Agency does not believe that a 2–year feeding study in the dog is of long enough duration to conclude that there are no carcinogenic effects of dichlorvos.

Comment. With regard to the mutagenicity of dichlorvos, the registrant states that ''dichlorvos has not been shown to present a significant risk of mutagenic effects to animals or humans.''

Agency Response. The comment did not include a discussion of results of mutagenicity studies conducted by the NTP in conjunction with conducting the bioassays on dichlorvos. Dichlorvos was found to be positive in two mammalian systems, for point mutations in the mouse L5178 lymphoma cell assay without metabolic activation (assay with activation was not done) and for sister chromatid exchanges in Chinese hamster ovary cells both with and without metabolic activation.

Comment. Amvac has supplied the Agency with additional information on the chronic rat inhalation study indicating that the test animals may have been exposed to substantially more dichlorvos than was measured in the inhalation chambers. The registrant estimated that the high-dose animals may have been exposed to 10 mg/rat/day, equivalent to 25 mg/kg/day in males and 34 mg/kg/day in females.

Agency Response. The Agency believes that the additional information provided by Amvac does not provide sufficient evidence to support adjusting the doses administered to the test animals.

Comment. Amvac stated that the dog study, which formed EPA's initial concern about liver toxicity, did not satisfy Subdivision F guidelines.

Agency Response. EPA has invalidated this study and liver effects are no longer of concern.

Comment. Pest Control Services, Inc. commented that the Agency overestimated the exposure for the No-Pest strip for use in museums.

Agency Response. First, EPA's exposure estimate was based on residential use where individuals are constantly exposed to dichlorvos. Because there are so many uses of dichlorvos, it is difficult to anticipate every possible exposure scenario. To protect the public health, the Agency focused on the high exposure scenario in the home. Use in museums (i.e., enclosed spaces such as display cabinets, display drawers, etc.) would be similar to that of grain silos, in that individuals would not be constantly exposed to the No-Pest Strip. Therefore, this preliminary determination does not propose any risk mitigation for use of No-Pest Strips in enclosed spaces in museums. In addition, an error in the Agency's 1987 exposure estimate has been corrected, reducing the residential exposure estimate from 9.6 mg/kg/yr to 0.93 mg/kg/yr. Even with this reduction in estimated exposure, the short-term and long-term MOEs for residential use are still far below 100.

III. Benefits Assessment

A. Summary of Benefits Assessment

EPA conducted a benefits assessment which concludes that the overall annual economic impact of a dichlorvos cancellation to users and consumers is not expected to be significant for most sites (Ref. 56). EPA knows of no major benefits from retaining most uses of dichlorvos with the probable exception of packaged or bagged nonperishable raw and processed food; poultry and livestock premises; feedlots; and possibly mushroom houses. Furthermore, for most of the individual dichlorvos use sites, a number of alternatives are registered and available. Any economic impacts are expected to diminish over time as users adjust to the alternative control measures. The major benefits of dichlorvos relate to its chemical properties: knockdown action and vapor activity. Its quick knockdown ability makes dichlorvos desirable for fly control, although it has little residual activity. In addition, dichlorvos is said to have vapor action which gives it penetration characteristics similar to a fumigant. Because of this characteristic, some users claim that there are no equivalent alternatives for certain uses.

B. Background

Dichlorvos, an organophosphate insecticide, kills insects on contact. Products containing dichlorvos are registered for use in controlling various invertebrate pests (insects, mites, spiders, scorpions, and sowbugs) in diverse situations. Dichlorvos is formulated alone and in combination with other active ingredients as emulsifiable concentrates, soluble concentrate liquids, granulars, pressurized liquids and dusts, smoke generators, impregnated materials, pellets/tablets, liquids (ready to use), total release aerosols, and wettable powders. Although dichlorvos has little residual activity, the knockdown action and vapor activity of the chemical are said to make it a versatile and effective chemical for pest control. Applications are made with aerosol and fogging equipment, smoke generators, hand-held sprayers, other ground spray equipment, and through slow release from impregnated materials, such as resin strips and pet collars. Amvac Chemical Corporation is the sole producer of technical grade dichlorvos in the United States. Dichlorvos is registered for use on a number of diverse indoor and outdoor sites.

C. Usage Information

Total annual usage of dichlorvos is estimated to range from about 250,000 to 500,000 pounds of active ingredient. The Agency believes that most of the dichlorvos is used for animal, livestock and premise treatments, and on bulk, packaged or bagged raw or processed food. EPA estimates that these sites account for between 45 and 83 percent of the dichlorvos used in the United States annually. Most of the remaining dichlorvos is used in greenhouses, homes, and mushroom houses.

D. Method

The approach of the benefits analysis was to evaluate, on the basis of available information, the potential economic impacts associated with the switch to alternative pest control technologies caused by the possible cancellation of certain dichlorvos uses. Future Agency action could change the availability and use of the alternatives. However, this analysis does not anticipate or speculate on the possible effects due to specific regulatory actions on the other chemical alternatives identified.

The following analysis is qualitative in scope. The information presented in the specific site assessments identifies the major pests controlled by dichlorvos for these sites, identifies the major registered alternatives and their availability, estimates the change in pest control costs associated with the use of the alternatives, and, where possible, evaluates impacts to users.

Usage estimates for the major dichlorvos use sites were based on various proprietary and non-proprietary usage data. Prices for dichlorvos and alternative products were based on pesticide product catalogues, quotes from pesticide distributors, and market surveys of consumer products. Determination of primary pests and major alternatives was based upon previous site-specific assessments prepared by a USDA/National Agricultural Pesticide Impact Assessment Program (NAPIAP)

Assessment Team, a DPRA Inc. Benefits Assessment (a private source of benefits information), and Preliminary Benefits Assessments (PBAs) by EPA. If specific site assessments were not available, then state recommendations, specimen label guides, the 1992 Insect Control Guide, and the EPA Index to Pesticide Chemicals provided information about the primary pests and alternative chemical controls for each site.

USDA completed a benefits assessment for dichlorvos in early 1990, based on survey data and expert opinion, that estimates the average annual benefit to be at least $120 million. This estimate was based on data from the mid-80's when usage was much higher than it is now. EPA estimates that dichlorvos usage has declined from approximately 2 million pounds annually at the time of the PD 1 (1985 data) to about 250,000 to 500,000 pounds per year at present. In addition, Amvac has requested voluntary deletion of several uses, which account for some of the current usage. Therefore, the use deletions will reduce usage even further.

In conducting the benefits assessment, each site was analyzed to determine the impacts that would result if dichlorvos were canceled for that site, (See Table 3 in this Unit). Comparative performance data were not available; therefore, the analyses were based on comparative cost assessments under the assumption that sufficient products were available which would provide adequate control of the pests.

The alternatives to dichlorvos include carbamates, organophosphates, natural pyrethrins and synthetic pyrethroid compounds. EPA has identified the following insecticides as likely alternatives to dichlorvos: bendiocarb, carbaryl, chlorpyrifos, diazinon, malathion, naled, phosmet, propoxur, permethrin, pyrethrins, resmethrin, and tetrachlorvinphos. In addition, non-chemical alternatives were also identified where information was available. In most cases these non-chemical alternatives help control insect populations which may result in a decrease in the frequency of chemical treatments. It is unlikely that these non-chemical alternatives would replace dichlorvos to the extent that a chemical alternative would.

E. Individual Sites

Table 3 in Unit III.F. of this document lists detailed information on the benefits for each site.

1. *In and around domestic buildings.* Dichlorvos is used in and around domestic buildings primarily as an aerosol treatment to control a variety of insects. It is also used in foggers and impregnated resin pest strips. A variety of chemical alternatives are available. In the absence of efficacy data, EPA is assuming that the alternatives would provide similar levels of control. Non-chemical alternatives are also available. EPA estimates that less than 1 percent of total dichlorvos is used in the home; however, it is unknown how much of this is applied by commercial applicators.

2. *Pets.* Dichlorvos is used to control fleas and ticks on dogs and cats through the use of impregnated plastic flea and tick pet collars. There are a variety of alternative chemicals available to dichlorvos, some of which have had reports of tick and flea resistance. Due to the lack of comparative efficacy and resistance data, EPA assumes that collars with and without dichlorvos have equal efficacy. There are also non-chemical alternatives available which can reduce the frequency of pesticide treatment, including: sanitation, vacuuming pet living and sleeping quarters, and washing or replacing bedding. EPA estimates that pet collars represent 3 percent of total dichlorvos usage. EPA does not expect the economic impact from cancellation of dichlorvos to be significant, because dichlorvos is not one of the major insecticides used in cat and dog collars.

3. *Mushroom houses.* Dichlorvos is used only as a space spray to control the adult mushroom fly complex after surface sprays and larvacides no longer provide adequate control; therefore, only permethrin is considered an actual alternative (Ref. 57). Non-chemical controls include black light traps to monitor fly emergence and quantify fly influx. There may be some pest resistance to both dichlorvos and permethrin; however, due to the lack of comparative efficacy or resistance data, EPA assumes that acceptable levels of control would be provided by both chemicals. EPA estimates that 2 percent of total dichlorvos is used on mushrooms. The Agency has information that suggests dichlorvos is primarily used as an emergency treatment if larval treatments fail. Economic impacts to the mushroom industry cannot be accurately assessed due to the limited usage data available regarding the use of the alternative chemicals. Based on limited information, some impacts are possible; however, economic impacts are not expected to be significant if dichlorvos is not available.

4. *Greenhouses.* Dichlorvos is used primarily as a space spray for control of a variety of insects on both food and nonfood greenhouse plants. The major direct alternatives, used as space sprays, aerosols, bombs, or pressure fumigators (smoke generators) include nicotine, pyrethrins, and resmethrin. There are also a variety of other alternatives used as greenhouse surface treatments and direct application to plants. There are reports that some whitefly species may be resistant to resmethrin; however, in the absence of comparative efficacy or resistance data EPA assumes that similar levels of control would be provided by the alternatives. Non-chemical mitigation measures to reduce pesticide applications include: sticky board traps, good sanitation practices and the use of insect free transplants. Total usage in greenhouses is less than 2 percent of total dichlorvos usage; however, available usage data do not separate food and non-food use of dichlorvos in greenhouses. If the number of applications is assumed to be equal for dichlorvos and the alternatives, then economic impacts resulting from the loss of dichlorvos are not expected to be significant.

5. *Direct application to animals and animal premises.* Dichlorvos is applied directly to domestic food and non-food animals primarily to control flies. Other insects are also controlled with dichlorvos (See Table 3 in Unit III.F. of this document). There are various alternatives available, which vary somewhat for each type of livestock and poultry. There are reports that flies are resistant to permethrin; however, in the absence of comparative efficacy or resistance data, EPA assumes that all products would perform similarly. Non-chemical control measures include the use of parasitic and predatory wasps that have not gained much commercial acceptance; upgraded/improved sanitary conditions involving manure management, trapping insects, and the introduction of bacteria and viruses that are pathogenic to the pests. Most uses on animals make use of some type of automatic method rather than hand-held application, therefore the loss of hand-held application should not result in a significant impact on users.

Dichlorvos is used as a space spray, animal spray, residual treatment, or bait in controlling flies in animal premises. There are a variety of chemical alternatives available. There are reports that flies are resistant to permethrin; however, in the absence of comparative efficacy or resistance data, EPA assumes that all products would perform similarly. Non-chemical controls include improved manure management, use of parasites, traps, sanitation, and electrocutors. EPA estimates the total usage for direct animal treatment and premise treatment for all domestic

animals is 100,000 to 200,000 pounds of active ingredient or between 27 percent and 54 percent of all dichlorvos usage. The actual cost of alternatives depends on the number of treatments needed to replace dichlorvos. Based on limited information, it is probable that some localized impacts would occur if dichlorvos were not available; however, EPA does not expect economic impacts to be significant overall (Refs. 58 and 59).

6. *Feedlots*. Dichlorvos is used in feedlots (including areas around feedlots, stockyards, corrals, holding pens, fences etc.) primarily as a space spray (fog) and as an indoor residual premise treatment to control flies. There are chemcial alternatives for space sprays and indoor residual premise sprays. Non-chemical alternatives include parasites, predators, and sanitation practices (removal of manure and organic matter). Based on information from USDA NAPIAP (Ref. 60) there are probable benefits from use of dichlorvos in feedlots. Depending on the alternative, loss of dichlorvos could result in cost increases or decreases. Overall, the economic impact due to loss of dichlorvos is not expected to be significant.

7. *Manure*. Dichlorvos is applied directly to manure (including dairy and beef cattle, and poultry) on farms to control flies. There are chemical alternatives for use as a direct manure treatment and as bait treatments. Non-chemical alternatives include the use of predators, parasites, insect traps, electrocutors, repellors, and removal of manure and organic matter. The cost per application is expected to be less for the alternatives. Therefore, the economic impact due to loss of dichlorvos is not expected to be significant.

8. *Garbage dumps*. Dichlorvos is used as a surface spray or bait treatment in garbage dumps to control flies. Chemical alternatives exist for each application method, all of which are believed to provide similar levels of fly control. The nonchemical alternative is sanitation - i.e. frequent removal or burial of garbage. Use of alternatives is expected to result in cost increases; however, actual costs would vary according to application rate and frequency. Because of the existance of chemical and non-chemical control measures, the economic impact due to loss of dichlorvos is not expected to be significant for this site.

9. *Ornamental lawns and turf*. Dichlorvos is used to control a variety of insects and related pests on these sites through the use of multi-active ingredient products. The major alternatives are considered to be equal to or superior to the efficacy of dichlorvos. Depending on the turf site and pest species, a wide variety of non-chemical control measures are available, including nematodes, flushing with water, improved management of turf, and use of resistant varieties of grass. EPA has no information suggesting that there is any significant usage of products containing dichlorvos on turf. The Agency believes that any such usage is likely to be by commercial applicators with multi-active ingredients containing both dichlorvos and chlorpyrifos. Because usage of products containing dichlorvos on turf appears to be negligible and the cost and efficacy of many of the alternatives are comparable to dichlorvos products, the impact of canceling dichlorvos on turf is expected to be negligible.

10. *Ornamental plants*. Dichlorvos is used on a variety of ornamental plants, including shade trees, hardwoods, flowering trees, conifers, evergreens, woody shrubs, vines, flowering plants and grasses (excluding turf). A variety of alternatives are used which depend on the pest and host plant. No comparative efficacy data are available; therefore, the Agency assumes that similar levels of control would be provided by all the chemicals listed in Table 3 in Unit III.F. of this document. Depending on the host plant and pest species, a wide variety of non-chemical control measures are available, including hand picking, sanitation, mulching, and improved cultural management. Dichlorvos usage information is not available. However, economic impacts are not expected to be significant due to the availability of several alternatives.

11. *Bulk, packaged or bagged nonperishable processed and raw food*. Dichlorvos is registered for use on bulk, packaged or bagged nonperishable processed and raw food to control a number of stored product insect pests. EPA believes that dichlorvos is used primarily as a space treatment with aerosols, foggers or as a fine stream applied to the cracks, crevices, and general storage areas of warehouses and similar facilities.

EPA believes that the major alternative to dichlorvos when used as a space treatment would be the pyrethrins. No comparative efficacy data for dichlorvos and pyrethrins are available to EPA at this time; therefore, EPA assumes that all the registered pesticides would provide adequate control of the pests. However, dichlorvos, unlike pyrethrins, is said to possess fumigant-like properties (high vapor pressure) and to rapidly penetrate throughout areas containing stacked commodities. Due to the different properties of dichlorvos and pyrethrins, EPA believes dichlorvos has the potential to be a more effective insecticide than pyrethrins by requiring fewer treatments to provide the same level of control in these situations. The Agency does not have data available to be able to estimate the number of applications needed for dichlorvos compared to pyrethrins. Without these data, the Agency can only estimate the cost difference on a per application basis.

The cost of treating 1,000 cubic feet would be $0.18 for pyrethrins and $0.04 for dichlorvos. Thus pyrethrins would cost $0.14 more than dichlorvos. EPA estimated that 50,000 to 75,000 lbs of the active ingredient of dichlorvos are applied to approximately 2 to 3 billion cubic feet of warehouse space for packaged or bagged nonperishable processed and raw food.

The characteristics of pyrethrins suggest that fumigations with methyl bromide or aluminum phosphide may be needed to supplement pyrethrins. Without the use of additional fumigants to supplement the pyrethrins, there could be some loss in overall control; however, EPA has no basis to confirm or estimate the resulting loss. EPA estimates the additional cost of using pyrethrins instead of dichlorvos to be $12 million per year. The additional cost of supplemental fumigations would be about $33 million with methyl bromide and $44 million per year with aluminum phosphide.

12. *Kennels*. Dichlorvos is used primarily as a residual surface spray for treating outside runways, window sills and ledges in kennels, to control fleas, ticks, flies, and mosquitoes. There are a variety of chemical alternatives available. There are reports of flea resistance to chlorpyrifos, propoxur, and carbaryl; however, due to the lack of comparative efficacy or resistance data, the Agency assumes similar levels of control would be provided by the various alternatives. Non-chemical alternatives include sanitation practices such as cleaning of kennels, laundering of bedding, and frequent changing of litter when used in combination with chemical treatment. There are no data on usage in kennels. No adverse economic impacts are expected to result from the cancellation of dichlorvos, since several alternatives are available and may cost less than dichlorvos per application.

13. *Insect traps*. Dichlorvos is used in pheromone traps to monitor heavy populations of gypsy moths and other insects in remote forested areas. In other situations adhesive coatings are used. Non-chemical adhesive coatings can be

as effective or more effective except when large numbers of insects entirely coat the strips. Economic impacts from cancellation would be negligible, since monitoring would only be less effective for heavy populations of insects.

14. *Commercial, institutional, and industrial areas.* Dichlorvos is used primarily as a residual surface spray or space treatment in restaurants, food processing and storage areas, transportation facilities, lodging, schools, and hospitals, to control a variety of insects. There are a variety of alternative chemicals; however, due to the lack of comparative efficacy data or resistance data, EPA assumes these alternatives will provide equal efficacy. Economic impacts are not expected to be significant if dichlorvos is canceled, although there could be a slight increase in costs from use of alternatives.

15. *Commercial transportation vehicles*—i. *Airplanes and buses.* Dichlorvos is used primarily as a space treatment in airplanes and buses for the control of a variety of pests including ants, cockroaches, fleas, flies, and quarantine pests. The major alternatives are phenothrin, pyrethrins, and resmethrin all of which are assumed to offer comparable efficacy to dichlorvos. No economic impacts are expected since current dichlorvos use is believed to be minimal.

ii. Trucks, shipholds, and railroad cars. Dichlorvos is used primarily as a space treatment in these vehicles primarily to control a variety of stored product pests. Major alternatives are pyrethrins and resmethrin, and equal efficacy to dichlorvos is assumed. A variety of non-chemical alternatives are available, including sanitation, modified atmospheres, irradiation, and controlled temperatures (hot and cold). Economic impacts are not expected to be significant, based on the availability of alternatives and the similarity in costs.

F. Strengths and Uncertainties of Benefits Assessment

The strengths of the benefits assessment include the identification of pests on which dichlorvos is used, alternative pesticides, methods of application, and application rates. There are also weaknesses in this benefits assessment: specific use and usage information is dated; many dichlorvos labels include a wide range of generalized use sites, making it difficult to describe specific uses (e.g. warehouses); comparative efficacy and product performance data do not exist for dichlorvos and its alternatives; there are no data regarding the number of treatments needed with an alternative to replace dichlorvos treatments; and there are no data regarding pest resistance to alternatives. Because of limited use and usage information, the benefits may be understated for fly control in feedlots, on livestock and livestock premises, and pest control in storage areas.

Little usage information for dichlorvos is available. Products containing dichlorvos come in several formulations, may be applied by several different methods, and can be used in many situations (for example, different types of warehouses); therefore, determining the usage for a particular site is difficult. The lack of comparative efficacy and product performance data also presented problems when trying to compare dichlorvos to the alternatives. This lack of data led the Agency to assume that all products listed would provide adequate control of the pests identified for each site unless otherwise noted. EPA is aware that some of the pests may be resistant to some of the chemicals listed; however, without supporting data the Agency cannot be more specific or come to a more definitive conclusion regarding the effectiveness of the chemicals. Other areas of difficulty involved determining the amount of product applied per application, the number of treatments needed, and the effect these factors had on the cost per application. For example, dichlorvos products are applied on the basis of cubic feet of space (as a space treatment), per square feet (as a surface treatment), some for a certain length of time, others as crack and crevice or spot treatments, some as baits, and still others directly to animals. This diversity of area treated and the number of applications needed or recommended (for example, based on the season, geographical area, and pests) created difficulties for making comparisons between products. Until more information is made available, the Agency assumes, for most sites, that single treatments are equivalent.

The Agency has no information regarding the use of dichlorvos on the following outdoor sites: Outdoor areas under the general category of farm buildings, outside surfaces of buildings, enclosed outdoor utility equipment, or urban and rural outdoor areas. Due to the complete lack of information, these sites have not been addressed in this assessment document. Table 3 below summarizes the benefits assessment for dichlorvos uses. In aggregate, the overall annual economic impact of a dichlorvos cancellation to users and consumers is expected to be negligible. Furthermore, for most of the individual dichlorvos use sites a number of alternatives are registered and available. Any economic impacts would be expected to diminish over time as uses adjusted to the use of these alternative control materials. EPA's benefits assessment is based on information currently available to the Agency. EPA would consider new information from interested parties that might modify this benefits assessment.

TABLE 3.—SUMMARY OF DICHLORVOS BENEFITS BY SITE

Site	Extent of Usage		Pests	Major Alternatives	Economic Impact Extent and Significance
	Lbs Active Ingredient/Year (Percent of Total Dichlorvos Use)**	Percent of Site Treated			
In and around domestic dwellings	3,000-4,000 (1%)	unknown	ants bees bedbugs cockroaches firebrats flies hornets mosquitoes silverfish spiders wasps yellow jackets	Aerosols (for homeowner use): bendiocarb chlorpyrifos diazinon malathion permethrin propoxur pyrethrins resmethrin	Not expected to be significant
Domestic animals (cats and dogs)	9,000-10,000 (3%)	unknown	American dog tick brown dog tick cat flea	Impregnated collars: carbaryl chlorpyrifos naled phosmet propoxur pyrethrins tetrachlorvinphos	Not expected to be significant
Mushroom House	6,000 - 7,000 (2%)	12.5% of site treated	phorid flies scairid files	Space spray: Permethrin	Possible impacts
Greenhouse uses: Ornamentals and Food crops (primarily cucumbers, lettuce, tomatoes)	Total Greenhouse usage for both ornamentals and food crops: 6,000-6,500 (2%)	unknown	aphids leafminers leafrollers mealybugs mites thrips whiteflies scale insects spider mites	malathion nicotine pyrethrins resmethrin	Not expected to be significant
Direct application to domestic food/non-food animals:	Total animal usage for direct application and their premises: 100,000-200,000 (27-54%)				
Livestock (beef and dairy cattle)		unknown	face fly stable fly house fly horn fly	coumaphos fenvalerate lindane malathion methoxychlor permethrin phosmet pyrethrins tetrachlorvinphos	Probable regional impacts
Poultry		unknown	northern fowl mite	carbaryl permethrin	Possible regional impacts

TABLE 3.—SUMMARY OF DICHLORVOS BENEFITS BY SITE—Continued

Site	Extent of Usage		Pests	Major Alternatives	Economic Impact Extent and Significance
	Lbs Active Ingredient/Year (Percent of Total Dichlorvos Use)**	Percent of Site Treated			
Horses (including ponies)		unknown	house fly stable fly face fly horn fly mosquitoes	permethrin pyrethrins tetrachlorvinphos	Possible regional impacts
Swine/hogs		unknown	house fly stable fly horse fly little house fly dump flies mosquitoes biting gnats psychodid flies screwworms	malathion permethrin tetrachlorvinphos	Possible regional impacts
Sheep/goats		unknown	horn fly house fly stable fly lice ticks sheep ked wool maggots	coumaphos diazinon fenvalerate lindane malathion methoxychlor permethrin	Possible regional impacts
In and around premises housing food and non-food animals:	Total animal usage for direct application and their premises: 100,000-200,000 (27-54%)				
Dairy rooms and milk houses		unknown	house fly	Space sprays: permethrin Surface sprays: fenvalerate malathion permethrin pyrethrins tetrachlorvinphos	Possible regional impacts
Furbearing animal units Such as mink farms		unknown	flies	methomyl (bait) permethrin pyrethrins tetrachlorvinphos	Possible regional impacts

TABLE 3.—SUMMARY OF DICHLORVOS BENEFITS BY SITE—Continued

Site	Extent of Usage		Pests	Major Alternatives	Economic Impact Extent and Significance
	Lbs Active Ingredient/Year (Percent of Total Dichlorvos Use)**	Percent of Site Treated			
Poultry houses		unknown	house fly (adult)	Space sprays: permethrin Surface sprays: dimethoate pyrethrins permethrin tetrachlorvinphos Bait applications: methomyl trichlorfon	Possible regional impacts
Feedlots, including around feedlots, stockyards, corrals, holding pens, fences, etc.	unknown	unknown	house fly stable fly horn fly face fly	Outdoor Space Sprays/Fog: malathion naled Residual Sprays: fenvalerate permethrin	Probable regional impacts
Manure (poultry and livestock manure) treatments on farm premises	unknown	unknown	house fly horn fly face fly	dimethoate malathion tetrachlorvinphos	Negligible
Ornamental lawns and turf	Little or no use expected	Little or no use expected	ants armyworm complex billbugs chiggers chinch bugs clover mite crickets cutworms earwigs fleas grasshoppers hyperodes weevils sod webworms ticks white grubs	For commercial applicator use only: acephate bendiocarb carbaryl chlorpyrifos diazinon isofenphos isazofos malathion	Negligible
Ornamental plants (excluding lawns and turf)	unknown	unknown	aphids bagworms borers cutworms eastern tent caterpillar gypsy moth leafhoppers mealybugs webworms mites spittlebugs whiteflies	acephate carbaryl chlorpyrifos diazinon malathion	Not expected to be significant

TABLE 3.—SUMMARY OF DICHLORVOS BENEFITS BY SITE—Continued

Site	Extent of Usage		Pests	Major Alternatives	Economic Impact Extent and Significance
	Lbs Active Ingredient/Year (Percent of Total Dichlorvos Use)**	Percent of Site Treated			
Nonperishable bulk-stored agricultural commodities (raw and processed)	20,000-35,000 (5-9%)	5%	almond moth angoumois grain moth cigarette beetle confused flour beetle flat grain beetle granary weevil Indianmeal moth lesser grain borer red flour beetle rice weevil sawtoothed grain beetle	Space sprays: pyrethrins	Not expected to be significant
Packaged or bagged nonperishable processed and raw food	50,000-75,000 (13-20%) for both raw and processed nonperishable packaged or bagged agricultural commodities	5-10% for both raw and processed nonperishable packaged or bagged agricultural commodities	almond moth angoumois grain moth cadelle cigarette beetle cockroaches confused flour beetle dermestid beetles drugstore beetle flat grain weevil granary weevil Indianmeal moth lesser grain borer Mediterranean flour moth merchant grain beetle red flour weevil rice weevil sawtoothed grain beetle tobacco moth	Space sprays: pyrethrins	$12 million for both raw and processed non-perishable packaged or bagged agricultural commodities plus the cost of additional fumigations if needed.
Kennels	unknown	unknown	fleas ticks house fly mosquitoes	carbaryl chlorpyrifos diazinon	Not expected to be significant
Insect traps (Monitoring purposes only)	50-100 (0.01-0.03%)	unknown	Adults of: gypsy moth spruce budworm forest tent caterpillar fruit flies codling moth corn borers weevils	None	Not expected to be significant

TABLE 3.—SUMMARY OF DICHLORVOS BENEFITS BY SITE—Continued

Site	Extent of Usage		Pests	Major Alternatives	Economic Impact Extent and Significance
	Lbs Active Ingredient/Year (Percent of Total Dichlorvos Use)**	Percent of Site Treated			
Garbage dumps	unknown	unknown	Flies (adults and maggots)	Surface sprays: chlorpyrifos diazinon propoxur Baits: methomyl trichlorfon	Not expected to be significant
Commercial, Institutional, and Industrial areas	unknown	unknown	ants cockroaches fleas flies moths silverfish sowbugs spiders stored product pests wasps	Surface sprays: chlorpyrifos cypermethrin diazinon propetamphos propoxur Aerosols: pyrethrins resmethrin	Not expected to be significant
Commercial transportation vehicles: Airplanes, buses	unknown	unknown	ants cockroaches fleas flies moths scorpions silverfish spiders ticks wasps quarantine pests	phenothrin pyrethrins resmethrin	Not expected to be significant

TABLE 3.—SUMMARY OF DICHLORVOS BENEFITS BY SITE—Continued

Site	Extent of Usage		Pests	Major Alternatives	Economic Impact Extent and Significance
	Lbs Active Ingredient/Year (Percent of Total Dichlorvos Use)**	Percent of Site Treated			
Other transportation vehicles including trucks, shipholds, and railroad cars			angoumois grain moth ants cadelle cheese mite cigarette beetle confused flour beetle dermestids drugstore beetle flat grain beetle granary weevil Indian meal moth lesser grain borer mealworms Mediterranean flour moth red flour beetle rice weevil sawtoothed grain beetle	pyrethrins	Not expected to be significant
Total usage accounted for above	250,000-500,000 (52-90%)				

**Note: The total used in calculating percentage of dichlorvos use for a given site is based on the mid point (375,000) of the total range 250,000 - 500,000.

G. Analysis of Comments

Comment. The Southeastern Peanut Association (SPA) commented that the substitutes to dichlorvos are substantially less effective on peanuts and not fully available for commercial use.

Agency response. The Agency cannot fully respond to this comment as the substitutes for dichlorvos were not identified in the letter from the SPA. The Agency has identified the pyrethrins as a possible alternative to dichlorvos. Because the pyrethrins are registered for use in much the same way as dichlorvos and due to the lack of comparative efficacy or resistance data, EPA assumes that they would provide acceptable levels of insect control. Regarding the availability of the pyrethrins, because the growing conditions that affect chrysanthemums (the source from which pyrethrins are derived) can vary from year-to-year, the Agency recognizes that the availability and price of pyrethrins will fluctuate as well.

Comment. The California Department of Food and Agriculture (CDFA) commented that dried fruit and tree nuts can be kept insect free if fumigated before entering storage and once in storage, receive regular treatments of dichlorvos. CDFA states that alternate methods of insect control, irradiation and controlled atmospheres are not feasible.

Agency response. The Agency believes that the pyrethrins would serve to control insects in the above situation if used in the same manner as dichlorvos. EPA does not have data that indicate the number of treatments needed for the pyrethrins to replace dichlorvos and still provide the same level of control. The Agency also believes that as the fumigant methyl bromide is phased out under the Clean Air Act, alternative measures such as irradiation, heat, cold, and controlled atmospheres will become more important.

Comment. The American Corn Millers Federation (ACMF) commented that the use of pyrethrins or resmethrin as alternatives to dichlorvos are not as efficacious in storage areas, warehouses, or processing areas of plants.

Agency response. The Agency has identified the pyrethrins and resmethrin (aerosol treatments) as potential alternatives to fogging with dichlorvos in commercial, industrial, and institutional areas. The ACMF did not submit data to support their contentions of inadequate efficacy of the alternatives. In the absence of comparative efficacy and/or resistance data, EPA assumes that these registered alternatives would provide adequate levels of insect control.

Comment. Two representatives from the popcorn industry commented that there are no replacements for the use of dichlorvos pest strips in popcorn storage facilities.

Agency response. The Agency has no specific information regarding insect control in stored popcorn; however, EPA does have information regarding

the treatment of other stored grain products. EPA believes the pyrethrins could be used as a head space treatment; however, EPA does not know how many treatments of pyrethrins it would take to provide the same level of control as obtained with the dichlorvos pest strips, which can last for several months.

Comment. The Department of Defense (DOD), Armed Forces Pest Management Board, commented on the use of dichlorvos as a fogging material in warehouses containing food products and textiles. The DOD lists pyrethroids, pyrethrins, aluminum phosphide, and the use of residual sprays as either not as effective or not as available as dichlorvos.

Agency response. In the most current benefits assessment, the Agency identified the pyrethrins and resmethrin as the most likely substitutes for dichlorvos when used as an aerosol or fog application. The Agency also listed products containing chlorpyrifos, cypermethrin, diazinon, propetamphos, or propoxur as surface residual treatments that could replace dichlorvos. In the absence of comparative efficacy or resistance data (DOD included no data with their comments), EPA has assumed that all registered alternative active ingredients would provide adequate control of the insect pests involved with these sites.

Comment. The Grocery Manufacturers of America (GMA) commented that the alternatives to dichlorvos were unsuitable because they are more expensive, less effective, require more frequent applications, and some may result in off-flavors to the stored foods.

Agency response. The GMA did not identify the alternatives and did not include any data to substantiate the contentions made. The Agency believes that dichlorvos is used primarily as an aerosol in commercial, industrial, and institutional areas. In the current benefits assessment, the Agency has identified resmethrin and pyrethrins as possible aerosol alternatives for dichlorvos and chlorpyrifos, cypermethrin, diazinon, propetamphos, or propoxur as residual surface treatments that could replace the use of dichlorvos. In the absence of comparative efficacy or resistance data, EPA assumes that all registered active ingredients listed would provide adequate pest control. EPA has no data regarding the off-flavoring of stored foods for any of the alternative products.

Comment. The National Food Processors Association (NFPA) commented that many of its members depend on dichlorvos for insect control in food processing plants, warehouses, and mushroom houses. NFPA stated that smaller amounts of dichlorvos are needed than the alternatives to control the pests, and that some pests have become resistant to the alternatives.

Agency response. NFPA did not include comparative efficacy and/or resistance data to support their contentions. In the current EPA benefits assessment of dichlorvos, EPA concludes that the use of surface sprays (diazinon, propoxur, or pyrethrins) and larvicides (diflubenzuron or methoprene) are the primary methods of insect control currently used in mushroom houses. In the absence of comparative efficacy or resistance data, EPA assumes that the alternative methods would provide adequate levels of control.

The Agency believes that dichlorvos is used primarily as an aerosol treatment in commercial, industrial, and institutional areas (including food processing plants and warehouses). In the current benefits assessment, the Agency identifies resmethrin and pyrethrins as possible alternatives for aerosol dichlorvos and chlorpyrifos, cypermethrin, diazinon, propetamphos, or propoxur as residual surface treatments that could replace the use of dichlorvos. In the absence of comparative efficacy and/or resistance data, EPA assumes that all registered active ingredients listed would provide adequate pest control.

Comment. A representative from the fumigation industry commented that the grain, seed, popcorn, and food processing industries do not need dichlorvos. Alternatives to dichlorvos were listed as pyrethrins, resmethrin, sanitation, monitoring with pheromone traps, and the use of grain protectants.

Agency response. In the current benefits assessment, EPA has identified several alternative active ingredients that could replace the use of dichlorvos in the above-mentioned areas. EPA also listed several non-chemical methods of insect control including sanitation, use of pheromone traps, predators, parasites, the use of heat or cold, exclusion, and irradiation. The Agency realizes that some of these methods may require more research before acceptance by industry and that many facilities would require additional construction before implementation could occur. In the absence of comparative efficacy or resistance data (none were included with the above comments), EPA assumes that the chemical alternatives to dichlorvos would provide adequate control of the insect pests. The Agency believes that the non-chemical methods cited could aid in insect control when used alone, in combination with each other, or in combination with insecticides.

Comments. Comments from the Pesticide Impact Assessment Program at the University of Idaho presented dichlorvos application and usage information for 1988 in the state of Idaho.

Agency response. While EPA appreciates and needs this type of information in order to conduct a benefits assessment, EPA believes the data gathered in 1988 may not be accurate at this time. The Agency believes that the volume of dichlorvos produced and sold in the United States has decreased over the last 5 to 6 years and assumes that this trend has occurred in Idaho as well.

Comment. Reliable Services commented that the loss of dichlorvos would be detrimental to the food related industries and that no effective alternatives exist for the use of dichlorvos strips in sewer catch basins for mosquito control. The alternatives identified for use in warehouses and food processing areas were identified as pyrethrins and resmethrin. Reliable Services estimates that for the alternatives, the number of applications are greater and the cost of materials are significantly higher than dichlorvos.

Agency response. Several pest strips containing dichlorvos are registered for use in catch basins to control adult mosquitoes. Although there are no direct alternatives for these pest strips, different formulations of other active ingredients are available that provide control of the larval and pupal stages of mosquitoes occurring in catch basins. EPA could find no state pest control guides recommending the use of pest strips for mosquito control at this particular site. EPA lacks sufficient use, usage, and efficacy data on dichlorvos to conduct a benefits assessment for this site/pest combination.

In the absence of comparative efficacy or resistance data, EPA assumes that all active ingredients listed would provide adequate pest control. The Agency also recognizes the importance of sanitation, exclusion, and trapping (pheromone traps) to control insect populations in storage facilities; however, EPA has no data indicating what percentage of insect control is accomplished by these methods.

Comment. The National Pest Control Association (NPCA) commented that dichlorvos is important to the structural pest control and food industries (transportation, storage, and processing facilities).

Agency response. EPA recognizes the important role dichlorvos has played in keeping insect populations under

control in the above areas. In the current benefits assessment, the Agency has identified alternative active ingredients (pyrethrins or resmethrin as aerosol sprays; chlorpyrifos, cypermethrin, diazinon, propetamphos, or propoxur as residual surface sprays) as well as non-chemical practices (sanitation, exclusion, heat, cold, modified atmospheres, pheromones, parasites, etc,) that, alone or in combination, may replace the use of dichlorvos. In the absence of comparative efficacy or resistance data, EPA assumes that the registered alternative active ingredients identified would provide adequate levels of insect control. EPA is not certain what percentage of insect control can be attributed to the non-chemical control methods discussed.

Comment. WHB Specialty Products Co. (WHB) commented that because of declining usage after 1983, any regulatory action taken by the U.S. EPA would have no economic impact on sales of their end-use products, which are used for control of insects on beef and dairy cattle and in livestock buildings.

Agency response. This comment is consistent with the Agency's information that usage is declining.

Comment. Consumers Union commented that the benefits of dichlorvos use in ''bug sprays,'' flea collars, and resin strips are negligible.

Agency response. EPA's current benefits assessment for dichlorvos has identified from one to several alternatives for the use of dichlorvos in ''bug sprays'' (In and Around Domestic Dwellings), resin strips (numerous sites), and pet flea collars (Domestic Animals). Based on the information available at this time, it is the Agency's opinion that the benefits for dichlorvos use in the areas mentioned above are negligible. In the absence of comparative efficacy or resistance data, EPA assumes that available registered alternatives would provide adequate control of the insect pests.

Comment. Amvac Chemical Corporation commented on the use of dichlorvos in warehouses and food processing areas. Amvac states that the alternatives are not as effective and are more expensive than dichlorvos.

Agency response. The current EPA benefits assessment (commercial, industrial, and institutional areas) and the comments from Amvac are in agreement as to pests controlled, primary methods in which dichlorvos is applied, and the potential alternatives to dichlorvos. Amvac states that the alternatives are not as effective as dichlorvos and refers to a survey and personal communications as the source for their conclusions. In the absence of comparative efficacy or resistance data, the Agency assumes that the registered alternatives would provide adequate control of the insect pests in warehouses and food processing plants. In addition, the Agency identified several non-chemical methods of insect control in warehouses and food processing facilities that Amvac did not include in their comments. EPA believes that in recent years alternative methods such as sanitation, exclusion, heat, cold, modified atmospheres, parasites, and the use of pheromone traps have become more common but the Agency has no data that identifies the percentage of insect control that can be attributed to these methods.

Comment. Amvac Chemical Corporation commented on the benefits and use of dichlorvos to control insects on dairy and beef cattle and in the premises housing these animals. Amvac states that resistance to some of the alternatives is a problem.

Agency response. The current EPA benefits assessment for dichlorvos includes the following sites that relate to food or nonfood animals and their premises: direct application to food and nonfood animals, in and around premises housing food and nonfood animals, manure treatments, and feedlots. The pests and their potential damage to animals, the primary methods of using dichlorvos, and the potential alternatives identified are similar in both the EPA assessment and Amvac's comments. EPA is aware that resistance to some of the alternatives may have occurred; however, EPA does not have any data identifying specific compounds, insect species, or the extent of any resistance problem. Amvac relied on personal communications and surveys to support their statements but did not submit data to substantiate their claims regarding efficacy or resistance. In the absence of comparative efficacy or resistance data, EPA assumes that all registered products would provide adequate insect control.

Comment. Amvac Chemical Corporation commented on the benefits and use of dichlorvos in domestic dwellings and in pet flea collars. Amvac states that the alternatives are not as efficacious as dichlorvos (based on personal communications) but includes no comparative efficacy and/or resistance data with their comments.

Agency response. In the current benefits assessment, EPA addressed these sites under the headings in and around domestic dwellings and domestic animals (Cats and Dogs). The EPA list of pests, primary methods of dichlorvos applications, and potential alternatives for these two sites was similar to the information provided by Amvac. In the absence of efficacy and/or resistance data, the Agency assumes that the identified registered alternatives would provide adequate control of the pests.

Comment. Amvac Chemical Corporation commented on the benefits and use of dichlorvos in food markets and eating establishments. Amvac stated that the alternatives are less effective and more costly.

Agency response. The section titled ''Commercial, Industrial, and Institutional Areas'' in the current EPA benefits assessment for dichlorvos includes information on eating establishments. Because of the lack of information, EPA did not include food markets in the benefits assessment. The EPA assessment for eating establishments included many of the same pests, the same primary methods of dichlorvos application, and the same potential alternatives as identified in the Amvac comments. Although Amvac states that the alternatives are less effective and more costly, they did not include supporting data with the comments. In the absence of data, the Agency assumes that the identified alternatives would provide adequate control of the pests.

Comment. Amvac Chemical Corporation commented on the benefits and use of dichlorvos resin strips in popcorn storage bins. Amvac identified the pyrethrins as a fogging treatment in bin head spaces or actellic (pirimiphos-methyl) as a protectant applied to the popcorn. Amvac states that neither the pyrethrins nor pirimiphos-methyl is as cost effective or efficacious as dichlorvos.

Agency response. The Agency has no specific information regarding insect control in stored popcorn and did not include this specific site in the current assessment; however, EPA does have information for the treatment of other stored grain products. The Agency believes that the pyrethrins can be used as a head space treatment; however, EPA has no information concerning the number of treatments of pyrethrins it would take to provide the same level of control as obtained with the dichlorvos pest strips. The dichlorvos impregnated resin pest strips can provide insect control for several months.

IV. Risk/Benefit Analysis and Proposed Regulatory Decisions

A. Summary of Risk/Benefit Analysis

EPA has concluded that the risks outweigh the benefits for most uses of dichlorvos, and therefore, proposes a

variety of measures to reduce risks to the acceptable level, including: Cancellation of some uses, requiring protective clothing, specifying reentry intervals, and restricting use to certified applicators. Tables 4 and 5, in this unit, summarize EPA's risk/benefit analyses and proposals for risk mitigation. The benefits are not expected to be significant for most sites, with the possible exceptions of packaged or bagged nonperishable raw and processed food, livestock, poultry, and mushroom houses. The lack of known significant benefits for most sites is outweighed by the potential total dietary cancer risk of 4.4 x 10^{-6} from use of dichlorvos and 5.1 x 10^{-6} from dichlorvos residues due to dichlorvos plus naled, and the occupational and residential risks involving several MOEs less than 100 (some less than 10) for ChE inhibition.

EPA considered measures short of cancellation to reduce occupational and residential risks, such as restricted reentry intervals, personal protective equipment, and restricting use to certified applicators. Where appropriate, these measures are proposed; however, cancellation is proposed for several uses because risk mitigation measures are not expected to reduce risk sufficiently.

There are a variety of alternatives available for dichlorvos, varying from use to use. EPA compared the toxicity of several alternatives for some major sites to understand the effect of canceling dichlorvos. This discussion of alternatives relates to the hazards posed by each pesticide in its technical form and does not take into account differing exposures resulting from application equipment used, or frequency or rate of application. The risk from a pesticide is a function of both the hazard or toxicity of the pesticide and the extent to which an individual is exposed. Alternatives fall into three chemical types, organophosphates, carbamates, and others. Organophosphates and carbamates inhibit ChE activity and result in neurotoxic effects. Several of the other alternatives are pyrethroids, including cypermethrin, permethrin, d-phenothrin and resmethrin. The pyrethrins and pyrethroid compounds present less of an acute hazard than the ChE-inhibiting alternatives. Exposure to the pyrethroids and pyrethrins can result in neurotoxicity, but the effects are rapidly reversible and only occur at much higher doses than for organophosphates. Pesticide poisoning incidents involving workers have been reported for several registered alternatives including, chlorpyrifos, diazinon, and malathion. Dichlorvos is a Group C (possible human) carcinogen, while for some alternatives there is no evidence of carcinogenicity or there are data gaps. Propoxur is a Group B2 (probable human) carcinogen and permethrin is a Group C. Dichlorvos has a higher cancer potency than either of these two chemicals. Also, the pyrethroids and pyrethrins are less toxic than dichlorvos following chronic exposure. Of all registered alternatives, only diazinon had an RfD lower than dichlorvos. Finally, no significant developmental or reproductive effects were reported for dichlorvos or any of the alternatives.

B. Proposed Regulatory Actions

1. *Dietary risk*. EPA is proposing cancellation of dichlorvos for use on bulk, packaged, and bagged nonperishable raw and processed food, because of the unacceptable risk posed by this use. Table 4, in this unit, compares the dietary cancer risk before and after the actions proposed in this notice. The estimated upperbound excess individual lifetime dietary cancer risk (before EPA's proposed action) from application of dichlorvos is 4.4 x 10^{-6} and from naled-derived dichlorvos is 7.2 x 10^{-7}, for a total of 5.1 x 10^{-6}. The major source of estimated dietary risk is packaged, bagged or bulk nonperishable processed or raw food (3.4 x 10^{-6}). The estimated risk from the three individual tolerances and FAR (bulk raw, packaged or bagged raw, and packaged or bagged processed) cannot be separated because, as discussed earlier, a single commodity may be treated more than once at different stages of production. Following EPA's proposed actions, discussed below, the remaining total dietary risk would be 1.7 x 10^{-6}, including dichlorvos derived from naled. This estimated dietary risk is believed to overestimate the actual risk because: (1) The estimated risk from naled residues is probably high because EPA assumed that the mosquito/fly control use (without regard to specific crops) would result in one percent of all commodities having residues; (2) EPA is assuming that 100 percent of the naled residues will metabolize into dichlorvos, which is probably not the case; and (3) the risk from milk (6.2 x 10^{-7} or about one-third of the risk after the proposed action) is believed to be an overestimate because the anticipated residues used in the risk assessment are based on one-half the limit of detection, which was used because no residues were found in milk following exaggerated application of dichlorvos. This dietary risk assessment could underestimate dietary risks from treated food in food handling establishments, since this risk in not included in the risk assessment; however, if the proposal to cancel use in commercial establishments, due to applicator and reentry risks, is finalized, this potential dietary risk will no longer exist.

2. *Use on bulk, packaged or bagged nonperishable raw and processed food*. EPA is proposing cancellation of these uses because of unacceptable dietary risks, and because of the unacceptable risk to workers from applying dichlorvos to stored food and reentering treated areas. (See paragraph 3--*Warehouses* in this unit.)

i. The estimated dietary risk from dichlorvos, 3.4 x 10^{-6}, is of concern because it exceeds the Agency's 10^{-6} negligible risk level. This group of uses is treated as one use here for purposes of risk estimation because consumption data do not permit a more detailed breakdown. This is an unusual site in that it is not specific to a location such as greenhouses or tobacco warehouses. Bulk, packaged, or bagged food can be found in a variety of locations including food handling establishments (food service, food manufacturing, and food processing establishments), in warehouses, shipholds, trucks and any other location where food is stored. Since the proportion of commodities stored in bulk compared to packaged/bagged food is unknown, it is not possible to clearly separate these risks or limit the scope of this proposal. Also, EPA does not believe that it is possible to reduce the frequency or amount of dichlorvos applications to decrease dietary risk to an acceptable level.

ii. There are potentially significant benefits for this use. The major alternatives are pyrethrins, and the absence of dichlorvos may require fumigant treatments. Cancellation of this use would result in increased costs estimated to be $12 million to replace dichlorvos with pyrethrins, plus, if needed, the additional cost of supplemental fumigations would be about $33 million with methyl bromide or $44 million per year with aluminum phosphide. Without the use of fumigants in supplementing pyrethrins there could be some loss in efficacy; however, EPA has no basis to confirm or estimate this loss. Although there are potential significant economic impacts, EPA believes that the dietary cancer risks to the general public outweigh the benefits. Therefore, EPA is proposing cancellation of use on bulk, packaged or bagged nonperishable raw and processed food. EPA is interested in comments on the effect of this proposal. The dietary risk discussed may also be affected by the pending revocation of the section 409 FAR for residues of dichlorvos on packaged or bagged

nonperishable processed food and the possible cancellation of the related uses. However, because those actions have not occurred, the Agency is proposing action at this time based on unacceptable dietary and worker risks (see warehouse discussion below).

3. *Warehouses*. MOEs from applying dichlorvos in warehouses and reentering treated areas are unacceptable, with the exception of impregnated resin pest strips in closed areas such as silos. EPA is, therefore, proposing cancellation of this use. Even if applicator exposure were minimized through the use of automatic application equipment, the MOEs from reentry would still be unacceptable. EPA assumes that a variety of tasks are performed in a warehouse including inventory, stocking and retrieving stored commodities, all of which would require entry into the warehouse soon after application to perform these tasks, and would result in prolonged exposure to a worker. Therefore, EPA does not believe it is feasible to mitigate the risk to workers reentering treated areas.

If dichlorvos can no longer be used in warehouses, areas where food is stored, due to worker risk, then the dietary risk from bulk stored, packaged or bagged raw and processed food would be eliminated. Therefore, the benefits for warehouses and for bulk stored, packaged or bagged food would be similar. As discussed in paragraph 2 above, there are potentially significant benefits for the use on bulk stored packaged and bagged food in warehouses. There are alternatives to dichlorvos for this use; however, cancellation of this use would result in increased costs as described in paragraph 2 above. These benefits do not justify MOEs of 38 for applicators and 2.8 for reentry workers. Based on unacceptable MOEs for applicators and reentry workers, EPA believes the risks outweigh the benefits, and therefore, products registered for the warehouse use should be canceled.

4. *Commercial, institutional, and industrial areas*. The risks posed by these uses, which include food handling establishments, are estimated to be similar to risks from warehouse uses, involving MOEs of 38 for applicators and 2.8 for persons reentering treated areas. There are a variety of registered alternatives in the absence of dichlorvos, and the benefits are not expected to be significant. EPA is, therefore, proposing to cancel these uses because the risks outweigh the benefits. Any dietary risk resulting from food handling use, although not estimated here, would be eliminated.

5. *Greenhouses*. The estimated dietary risk from dichlorvos use in greenhouses is 2.0×10^{-7}, which is negligible. However, the MOEs for workers performing most methods of application in greenhouses are less than 100, and about one-third are less than 50, since they involve the applicator remaining in the greenhouse during application. In addition, the MOE for reentry workers 24 hours after application is 21. There are a variety of registered alternatives available as a space treatment, surface treatment or direct treatment to plants. Assuming an equal number of applications to replace dichlorvos, the cancellation of dichlorvos should not result in significant economic impacts. These applicator and reentry risks are unacceptable, and thus, EPA is proposing to cancel registrations of products labeled for use in greenhouses unless the following changes are made to the label which will reduce risks to an acceptable level: Eliminate hand-held application methods and require use of automatic foggers inside the greenhouse or fogging through a port on the side of a greenhouse. In either case, no one (including the applicator) would be allowed in the greenhouse during the application. In addition, because of low MOEs for workers reentering greenhouses, the Agency is proposing to limit exposure by prohibiting entry by anyone, including handlers (except in an emergency) within the first 4 hours following application. For the remainder of the first 48 hours following application, the Agency is proposing to allow one hour per day entry into dichlorvos-treated greenhouses by trained pesticide handlers who are equipped with handler personal protective equipment (including an organic-vapor-cartridge respirator) and who are performing a handling task. Handling tasks are defined by the Worker Protection Standard (40 CFR part 170) and include operating ventilation equipment and checking air concentration levels. Entry by workers to perform non-handler tasks, such as harvesting, cultivation, and irrigation-related tasks would be prohibited for the entire 48–hour period. It is unclear what effect, if any, the reentry restrictions proposed in this action will have on the greenhouse industry, since the Agency has no information regarding the need for reentry tasks during the first 48 hours following application of dichlorvos.

If the application and reentry restrictions proposed here are not feasible to implement, EPA does not believe that the loss of dichlorvos in greenhouses would have a significant impact on the greenhouse industry; benefits from the use of dichlorvos in greenhouses are expected to be minimal due to the availability of alternatives. Therefore, EPA is proposing these restrictions because, without them, the applicator and reentry risks outweigh the benefits. Note that the entry restrictions being proposed by the Agency are based on the assumption that the treated area would not be ventilated for the entire 48–hour period following application. The Agency would consider data, if submitted, that indicate that a specified number of air exchanges or a specified number of hours of mechanical ventilation would reduce the dichlorvos air concentration level to an acceptable level for safe entry for workers (without respirators) in less than the proposed 48–hour entry-restricted period. This 48–hour reentry period exceeds the 24–hour period required in the Worker Protection Standard; however, based on the exposure data for dichlorvos, EPA believes that this longer reentry period is necessary to reduce worker risk to an acceptable level.

6. *Mushroom houses*. The estimated dietary risk from use of dichlorvos in mushroom houses is 2.6×10^{-9}, which is negligible. However, the MOEs for most methods of applying dichlorvos in mushroom houses are less than 100, and some are less than 10, since they involve the applicator remaining in the house during application. In addition, the MOE for reentry workers following 24 hours after application is 21. These applicator and reentry risks are unacceptable, and thus, EPA is proposing to cancel registrations of products labeled for use in mushroom houses unless the following changes are made to the label which will reduce risks to an acceptable level: Eliminate hand-held application methods, and require use of automatic foggers inside the mushroom house or fogging through a port on the side of a mushroom house. In either case, no one (including the applicator) would be allowed in the mushroom house during the application. In addition, because of low MOEs from reentering mushroom houses, the Agency is proposing to limit exposure by prohibiting entry by anyone, including handlers (except in an emergency) within the first 4 hours following application. For the remainder of the first 48 hours following application, the Agency is proposing to allow one hour per day entry into dichlorvos-treated mushroom houses by trained pesticide handlers who are equipped with handler personal protective equipment (including an

organic-vapor-cartridge respirator) and who are performing a handling task. Handling tasks are defined by the Worker Protection Standard (40 CFR part 170) and include operating ventilation equipment and checking air concentration levels. Entry by workers to perform non-handler tasks, such as harvesting, cultivation, and irrigation-related tasks would be prohibited for the entire 48–hour period. The economic impact resulting from these restrictions is not expected to be significant since dichlorvos is only used for insect control after surface sprays and larvacides have been used, and permethrin is available as a direct alternative to dichlorvos. It is unclear what effect, if any, the reentry restrictions proposed in this action will have on the mushroom industry, since the Agency has no information showing whether reentry to perform crop cultivation tasks is necessary during the first 48 hours following application. EPA acknowledges that there may be impacts due to these restrictions; however in the absence of data, EPA is assuming no impact. Therefore, EPA is proposing these restrictions because, without them, the applicator and reentry risks outweigh the benefits. Note that the entry restrictions being proposed by the Agency are based on the assumption that the treated area would not be ventilated at all during the entire 48–hour period following application. The Agency would consider data, if submitted, that indicate that a specified number of air exchanges or a specified number of hours of mechanical ventilation would reduce the dichlorvos air concentration level to an acceptable level for safe entry for workers (without respirators) in less than the proposed 48–hour entry-restricted period. This 48–hour reentry period exceeds the 24–hour period required in the Worker Protection Standard; however, based on exposure data for dichlorvos, EPA believes that this longer reentry period is necessary to reduce worker risk to an acceptable level.

7. *Direct treatment to domestic food and non-food animals (non-poultry).* EPA is proposing cancellation of all products registered for hand-held application methods to domestic animals. The MOE for hand application is approximately 6. Other direct application methods that do not involve hand-held application are not expected to exceed the Agency's level of concern and would still be allowed. These include: face and back rubbers, and devices which automatically apply dichlorvos to the animals. The loss of dichlorvos for hand-held treatment of animals should not have a major economic impact since there are easily available alternatives similar in cost to dichlorvos, and dichlorvos can still be used by other methods. Therefore, EPA believes that the risks outweigh the benefits for hand-held methods of application to food and non-food animals, excluding poultry.

8. *Direct treatment to domestic food and non-food animals (poultry).* EPA is proposing to retain the use of dichlorvos on poultry because the risks from application are not unreasonable. Dichlorvos is mainly used as a space spray to treat poultry premises, but it is also used for direct animal treatment. EPA does not have data to estimate risk from treating poultry; however, the Agency believes that both the application method and fewer number of applications will result in much lower exposure and risk than for cattle treatment. The benefits for poultry treatment cannot be separated out from the use on domestic animals and their premises. However, EPA believes there is a benefit for controlling mites on laying hens. As a result EPA is believes the benefits of dichlorvos use exceeds the risks and is proposing retention of this use.

9. *Treatment of domestic animal (food and non-food) premises.* EPA is proposing to retain the use of dichlorvos for treatment of domestic animal premises. The Agency estimates that MOEs for applying dichlorvos are greater than 100. Because there may be some benefits for the combined direct animal and premise treatment, and the estimated risk is very low, EPA believes that the benefits of this use outweigh the risks. Therefore, EPA is proposing retention of this use.

10. *Feedlots (including around feedlots, stockyards, corrals, and holding pens).* EPA proposes to retain the use of dichlorvos in feedlots. The Agency estimates that the MOEs for applying dichlorvos are greater than 100. Also application of dichlorvos in feedlots generally involves application over a short period of time in a well ventilated area, which together, further reduces the risk of exposure. There are various alternatives to dichlorvos for controlling flies in feedlots. Because there are probable regional impacts resulting from cancellation of this use, and the MOEs are greater than 100, EPA is proposing to retain this use. Therefore, the benefits outweigh the risks in this case.

11. *Manure.* EPA proposes retaining the use of dichlorvos on manure. The Agency estimates that the MOEs for applying dichlorvos on manure are greater than 100. In addition, manure is generally located outdoors or in well-ventilated areas, thereby reducing exposure to dichlorvos. There are various alternatives to dichlorvos for controlling flies on manure. There may be some benefits from the use of dichlorvos on manure, although not significant, and because this use is not a risk of concern, EPA is proposing to retain the use on manure.

12. *Tobacco warehouse.* EPA is proposing cancellation of products registered for this use because both applicator and reentry MOEs are low: 2 for application and 0.3 for reentry. Although EPA did not conduct a benefits analysis for this use site, EPA believes that little or no dichlorvos is used for tobacco warehouses, and Amvac has requested voluntary cancellation for this use site. The Agency does not anticipate a significant economic impact from cancellation; therefore, the risks of this use outweigh its benefits.

13. *Residential uses.* The Agency is proposing cancellation of all products registered for residential uses, including use by residents and by professional applicators, and for use on pets. EPA has determined that the MOEs are significantly less than 100 for all methods of application in the home and for post-application exposure to residents. The animal health and safety data discussed earlier also indicate an unacceptable risk for pets. Overall, the effect of cancellation of all residential uses is not expected to be significant, since there are several alternatives available. Therefore, EPA believes that the risks to residents and pets outweigh the benefits of this use.

14. *Ornamental lawns, turf and plants.* EPA is proposing to cancel dichlorvos products registered for these uses. The estimated risks from application of dichlorvos to ornamental lawns, turf, and plants are low (32 - similar to a greenhouse power sprayer). The economic impact resulting from the cancellation of this use is not expected to be significant since there are alternatives available which, in some cases, cost less than dichlorvos. Therefore, the risks outweigh the benefits.

15. *Kennels.* EPA is proposing to retain use in kennels. The Agency estimates that the MOE for applying dichlorvos in kennels is similar to that of a dairy barn or at least 225. There may be some benefits from the use of dichlorvos in kennels, although not significant, and because this use is not a risk of concern, EPA is proposing to retain this use.

16. *Insect traps*. EPA is proposing to retain the use of dichlorvos in insect traps. The risk to applicators is expected to be negligible because of the short amount of time that the applicator is in contact with the trap, and because the traps are located outside away from people. The only alternative, adhesive strips, may not be as effective as dichlorvos in cases where there are heavy insect populations. Although the overall benefits are not expected to be significant, the benefits for heavy insect problems outweigh the negligible risks.

17. *Garbage dumps*. EPA proposes retaining the use of dichlorvos on garbage dumps. The Agency estimates that the MOE for applying dichlorvos on a garbage dump are greater than 100. In addition, garbage is generally located outdoors or in a separate room, thereby reducing exposure. There are various alternatives to dichlorvos for controlling flies on garbage. There may be some benefits from the use of dichlorvos on garbage dumps, although not significant, and because this use is not a risk of concern, EPA is proposing to retain the use on garbage dumps.

18. *Commercial transportation vehicles*. There are unacceptable applicator and reentry risks for all commercial transportation uses. Due to a very low MOE of 14 for applicators on airplanes, EPA is proposing to cancel dichlorvos products registered for this use. EPA does not believe it is possible to reduce this risk. The benefits are not expected to be significant, since EPA estimates the use to be minimal and Amvac has requested voluntary cancellation of this use. Therefore, EPA believes the risks outweigh the benefits of continued use in airplanes.

The Agency believes that risk mitigation measures are possible for use of dichlorvos in buses. For passenger buses, EPA is proposing to eliminate applicator exposure by limiting application to only foggers, and requiring a 6–hour ventilation period following treatment. With these measures required, the benefits of use of dichlorvos in buses would outweigh its risk.

EPA is proposing to cancel products registered for use in other vehicles (trucks/shipholds/railroad cars). EPA does not believe it is feasible to mitigate the risk from reentry. A 36–hour reentry period would be required to achieve an MOE above 100, which is not practical for commercial vehicles. The economic impact resulting from the cancellation of this use is not expected to be significant since there are alternatives available which would result in similar treatment costs. Therefore, the risks outweigh the benefits.

19. *Restricted use*. With the exception of certain uses listed below, EPA is proposing that all registered products be restricted to use by certified applicators only. This proposal is based on the acute toxicity of dichlorvos (Toxicity Category I, the most toxic classification) and the existence of poisoning incidents. This is not expected to be a major burden since most commercial use products already have a label statement limiting sale and use to pest control operators. In addition, the Registration Standard recommended classification of all products, except those labeled for household use only, as restricted use. EPA is therefore proposing to restrict the use of all products except those registered for only the following uses: impregnated strips in enclosed spaces within a museum and insect traps.

20. *PPE requirements*. EPA proposes to cancel the registration of all remaining dichlorvos products unless the labels are amended to require users to wear: a long sleeved shirt, long pants, gloves, socks and shoes. EPA estimates of acceptable MOEs for some uses are based on wearing these protective clothing. The PPE proposed in this Notice are the minimum needed to eliminate unreasonable risks from use of dichlorvos. If the presence of additional active ingredients in specific end-use products result in more restrictive PPE requirements then the more restrictive requirements must be placed on the end-use label.

If the acute inhalation toxicity of the end-use product is in category I or II, and therefore, a respirator is required for pesticide handlers, the following type of respirator is appropriate to mitigate dichlorvos inhalation concerns: a respirator with either an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).

21. *Retained uses*. EPA is proposing to retain the following uses; however, the related registrations will be canceled unless the labels conform to the above cancellations, restricted use, reentry and protective clothing requirements: mushroom houses and greenhouses (only automatic foggers or fogging through a port), kennels, feedlots, insect traps, garbage dumps, direct application to poultry, automated application to livestock, animal premises, manure, and buses.

TABLE 4.—UPPER BOUND CANCER RISK ESTIMATES FROM USE OF DICHLORVOS AND NALED

Use	Risk Before Agency Proposed Action	Risk After Agency Proposed Action
Packaged or bagged, non-perishable processed food and RACs (including bulk stored, regardless of fat content)	3.4×10^{-6}	0
Milk	6.2×10^{-7}	6.2×10^{-7}
Eggs	7.1×10^{-8}	7.1×10^{-8}
Red Meat	1.1×10^{-7}	1.1×10^{-7}
Poultry	3.7×10^{-8}	3.7×10^{-8}
Agricultural uses	2.1×10^{-7}	2.1×10^{-7}
Lettuce	1.6×10^{-7}	1.6×10^{-7}
Cucumbers	2.6×10^{-8}	2.6×10^{-8}
Tomatoes	1.4×10^{-8}	1.4×10^{-8}

TABLE 4.—UPPER BOUND CANCER RISK ESTIMATES FROM USE OF DICHLORVOS AND NALED—Continued

Use	Risk Before Agency Proposed Action	Risk After Agency Proposed Action
Mushrooms	2.6×10^{-9}	2.6×10^{-9}
Radishes	9.8×10^{-10}	9.8×10^{-10}
Dichlorvos from application of:		
Dichlorvos	4.4×10^{-6}	1×10^{-6}
Naled	7.2×10^{-7}	7.2×10^{-7}
Total	5.1×10^{-6}	1.7×10^{-6}

TABLE 5.—SUMMARY OF DICHLORVOS RISKS AND BENEFITS

Uses	Non-Dietary Margin of Exposure: Cholinesterase Inhibition	Dietary Upper Bound Cancer Risk	Benefits	Proposed Action
Domestic Dwellings (Application)				
Pressurized Aerosol	47	N/A	Benefits in and around domestic dwellings are not expected to be significant	Cancel
Crack and crevice treatment	23	N/A		Cancel
Domestic Dwellings (Post-Application)				
Total release fogger	17	N/A	Benefits in and around domestic dwellings are not expected to be significant	Cancel
Pressurized Aerosol	17	N/A		Cancel
Crack and crevice treatment	2	N/A		Cancel
Resin Pest strips	20	N/A		Cancel
Pet Flea collars	240	N/A		Cancel
Occupational Exposure				
Mushroom House Applicator	Majority of MOEs less than 50 and some less than 10	2.6×10^{-9}	Benefits are not expected to be significant	**Allowable Application Methods** -Automatic foggers -Thermal foggers through a port **Application Methods Not Allowed (Cancel)** -Hand application or any method in which the applicator remains inside the mushroom house during application.

TABLE 5.—SUMMARY OF DICHLORVOS RISKS AND BENEFITS—Continued

Uses	Non-Dietary Margin of Exposure: Cholinesterase Inhibition	Dietary Upper Bound Cancer Risk	Benefits	Proposed Action
Reentry After 24 hours After 48 hours	21 (no respirator) 289 (no respirator)			Reentry Restrictions Limited reentry during first 48 hours following treatment. No entry within first 4 hours; limited reentry (one hour per 24 hours) for handling activities only.
Greenhouse Applicator	Majority of MOEs less than 100 and 30% less than 50	1.6×10^{-7} (lettuce) 2.6×10^{-8} (cucumbers) 1.4×10^{-8} (tomatoes) 8.8×10^{-10} (radishes)	Not expected to be significant	**Allowable Application Methods** -Automatic foggers -Thermal foggers through a port **Application Methods Not Allowed (Cancel)** -Hand application or any method in which the applicator remains inside the greenhouse during application.
Reentry After 24 hours After 48 hours	21 (no respirator) 289 (no respirator)			Reentry Restrictions Limited reentry during first 48 hours following treatment. No entry within first 4 hours; limited reentry (one hour per 24 hours) for handling activities only.
Domestic food/nonfood animals (non-poultry) Applicator	6.1	6.2×10^{-7} (milk)	Probable regional impacts	Cancel all hand application methods to both food and nonfood animals

TABLE 5.—SUMMARY OF DICHLORVOS RISKS AND BENEFITS—Continued

Uses	Non-Dietary Margin of Exposure: Cholinesterase Inhibition	Dietary Upper Bound Cancer Risk	Benefits	Proposed Action
		1.1×10^{-7} (red meat)		Other uses are permitted such as back and face rubbers, and automatic application systems.
Domestic food/nonfood animals (poultry)	> 100	7.1×10^{-8} (eggs) 3.7×10^{-8} (poultry)	Possible regional impacts	Retain Use
Domestic animal premises (food and non-food) (includes dairy barns, mink farms, barns, stables, poultry houses)				
Applicator	> 100	N/A	Probable regional impacts	Retain uses
Reentry	> 100	N/A		
Feedlots	>100	N/A	Probable regional impacts	Retain use
Manure	>100	N/A	Benefits not expected to be significant	Retain use
Tobacco warehouse		N/A	Benefits not expected to be significant	Cancel
Applicator-sprinkling	2			
Mixer-loader	32,500			
Warehouse worker (reentry)	0.3			
Ornamental lawns, turf and plants	32 (similar to greenhouse power sprayer)	N/A	Not expected to be significant	Cancel
Warehouse treatment (affects nonperishable bulk, packaged and bagged raw and processed commodities)				
Application	38	3.4×10^{-6}	$12 million for both raw and processed nonperishable bulk, packaged, or bagged agricultural commodities plus the cost of additional fumigations if needed.	Cancel all application methods except for impregnated resin strips which are limited to closed areas such as silos.
Reentry	2.8			
Kennels	> 100 (similar to dairy barn)	N/A	Not expected to be significant	Retain use

TABLE 5.—SUMMARY OF DICHLORVOS RISKS AND BENEFITS—Continued

Uses	Non-Dietary Margin of Exposure: Cholinesterase Inhibition	Dietary Upper Bound Cancer Risk	Benefits	Proposed Action
Insect traps Applicator	negligible risk	N/A	Not expected to be significant	Retain use
Garbage dumps	> 81 (less than greenhouse risk)	N/A	Not expected to be significant	Retain use
Commercial, institutional and industrial areas (includes food service, food processing, end food manufacturing possibilities) Applicator Reentry	38 2.8	Potential dietary risks	Not expected to be significant	Cancel all uses
Commercial transportation vehicles				
Airplanes (disinsection of aircraft) Passenger - post-application Applicator	135 14	N/A	Not expected to be significant	Cancel use on airplanes
Buses-passenger	55	N/A	Not expected to be significant	Retain only fogger use on buses and require a 6–hour ventilation period before reentry.
Truck, shipholds, rail cars Application Reentry	> warehouse 20	Potential dietary risk	Not expected to be significant	Cancel use

NOTE: Amvac has requested voluntary deletion of the following uses from their technical and end-use labels. In response to the Federal Register Notice announcing Amvac's request, no one expressed interest in retaining these uses, with the exception of greenhouses and outdoor household use. Therefore, the Agency intends to follow through with Amvac's request to delete these uses, excluding the two exceptions. Any risks associated with these uses will be eliminated.

- Domestic dwellings (except for impregnated resin pest strips, total release foggers, and crack and crevice treatment). There is interest in supporting outdoor household use and this use will not be immediately deleted. However, based on risk/benefit considerations, the Agency is proposing to cancel this use.

- Greenhouses. Because there is interest in supporting use in greenhouses, this use will not be immediately deleted. However, based on risk/benefit considerations, the Agency is proposing to cancel this use, unless certain use restrictions are put into place.

- Tobacco and tobacco warehouses

- Food service establishments, food manufacturing establishments and food processing establishments, with the exception of nonfood-processing areas. - Aircraft and buses

The following uses which Amvac is requesting to delete are not included in the above risk/benefit table: tomatoes, rangeland grasses, and aerial application.

V. Existing Stocks

Under the authority of FIFRA section 6(a)(1), EPA will establish certain limitations on the distribution and use of existing stocks of dichlorvos products subject to any final cancellation notice. EPA defines the term ''existing stock'' to mean any quantity of dichlorvos products in the United States on the effective date of the Final Notice of Intent To Cancel certain registrations, or on the effective date an application for amendment of registration is granted by the Agency. Such existing stocks include dichlorvos products that have been formulated, packaged, and labeled and are being held for shipment or release or have been shipped or released into commerce.

EPA is proposing not to permit the continued sale, distribution, or use of dichlorvos products affected by this Notice after the effective date of the Final Cancellation Notice. EPA reserves the right to amend this existing stocks provision, should conditions warrant

such amendment. The final cancellation notice may amend the existing stocks provisions in the Use Deletion Notice published on April 19, 1995 (60 FR 19580).

VI. Procedural Matters

As required by FIFRA sections 6(b) and 25(d), and 40 CFR 154.31(b), EPA has transmitted copies of a draft Notice of Intent to Cancel based on this Notice, together with the support documents, to the Secretary of Agriculture and the Scientific Advisory Panel for comment. EPA will publish any comments received from the Secretary or the Panel, and EPA's responses, in the Notice of Final Determination.

VII. Public Record and Opportunity for Comment

The Agency is providing a 90–day period for the public to comment on this Notice and on the dichlorvos Special Review Docket. Comments must be submitted by December 27, 1995. All comments and information should be submitted in triplicate to the address given in the Notice under ''ADDRESSES.'' All comments should be identified with the public docket number (OPP–30000/56). All comments, information, and analyses which come to the attention of EPA may serve as a basis for final determination of regulatory action during the Special Review.

A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this Notice, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

VIII. Public Docket

Pursuant to 40 CFR 154.15, the Agency has established a public docket [OPP-30000/56] for the dichlorvos Special Review. This public docket will include: (1) This Notice; (2) any other notices pertinent to the dichlorvos Special Review; (3) non-CBI documents and copies of written comments submitted to the Agency in response to the pre-Special Review registrant notification, the Federal Register Notice initiating Special Review, this Notice, any other Notice regarding dichlorvos submitted at any time during the Pre-Special Review process by persons outside government; (4) a transcript of any public meetings held by EPA for the purpose of gathering information on dichlorvos; (5) memoranda describing each meeting held during the Special Review process between Agency personnel and persons outside government pertaining to dichlorvos; and (6) a current index of materials in the public docket.

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List of Subjects

Environmental protection.

Dated: September 22, 1995.

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