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 nonfood 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

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