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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D. C. 20548



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FOR RELEASE ON DELIVERY
EXPECTED AT 4 P.M., EST
THURSDAY, MAY 1, 1980

STATEMENT OF
HUGH J. WESSINGER, ASSOCIATE DIRECTOR
SENIOR LEVEL
COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION

BEFORE THE
SUBCOMMITTEE ON DEPARTMENT INVESTIGATIONS,
OVERSIGHT AND RESEARCH
OF THE
HOUSE COMMITTEE ON AGRICULTURE
ON

THE ENVIRONMENTAL PROTECTION AGENCY'S
PROCEDURES FOR SUSPENDING A PESTICIDE

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

WE WELCOME YOUR INVITATION TO DISCUSS THE PRELIMINARY
RESULTS OF OUR REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S
(EPA'S) PROCEDURES FOR SUSPENDING A PESTICIDE'S USE. WE BEGAN
THIS REVIEW IN RESPONSE TO A MARCH 11, 1980, REQUEST FROM
CONGRESSMAN WILLIAM C. WAMPLER, THE COMMITTEE'S RANKING
MINORITY MEMBER, WHO WAS CONCERNED THAT EPA'S EMERGENCY
SUSPENSION OF MAJOR USES OF THE PESTICIDES 2,4,5-T AND
SILVEX MAY NOT HAVE BEEN BASED ON SCIENTIFICALLY VALIDATED
STUDIES.

WE WERE ALSO REQUESTED TO EXPLORE WHETHER THERE IS A
NEED TO AMEND THE PROVISIONS OF THE FEDERAL INSECTICIDE,
FUNGICIDE, AND RODENTICIDE ACT (FIFRA) CONCERNING EPA'S

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SUBMISSION OF A PROPOSED NOTICE OF INTENT TO CANCEL A PESTICIDE TO THE SCIENTIFIC ADVISORY PANEL FOR ITS REVIEW AND COMMENT BEFORE TAKING REGULATORY ACTION.

FIRST LET ME BRIEFLY MENTION SOME OF THE EVENTS THAT LED TO EPA'S SUSPENSION OF MAJOR USES OF 2,4,5-T AND SILVEX AND ITS INITIATION OF CANCELLATION HEARINGS ON ALL USES OF THESE PESTICIDES.

HISTORY OF FEDERAL REGULATION
OF 2,4,5-T AND SILVEX

THE HERBICIDE 2,4,5-T HAS BEEN USED PRIMARILY TO KILL OR CONTROL UNDESIRABLE VEGETATION IN FORESTS, RANGE AND PASTURE LANDS, RIGHTS-OF-WAY, AND RICE FIELDS. SILVEX HAS SIMILAR USES, INCLUDING USES AROUND THE HOME AND GARDEN.

THE TOXICITY OF 2,4,5-T AND ITS PRODUCTION CONTAMINANT DIOXIN BECAME THE FOCUS OF REGULATORY CONCERN EVEN BEFORE EPA HAD ASSUMED RESPONSIBILITY FOR PESTICIDE REGULATION, IN DECEMBER 1970. THE U.S. DEPARTMENT OF AGRICULTURE, ⁴² IN EARLY 1970, HAD SUSPENDED USES OF 2,4,5-T IN WATERBODIES, AROUND THE HOME, AND ON FOOD CROPS. EPA LATER ALLOWED ITS USE ON RICE FIELDS.

IN JULY 1973, EPA BEGAN CANCELLATION PROCEEDINGS AGAINST THE REMAINING USES OF 2,4,5-T, INCLUDING FORESTRY, RANGE LAND, RICE, AND RIGHTS-OF-WAY USES. HOWEVER, IN JUNE 1974, EPA DISCONTINUED THE PROCEEDINGS IN ORDER TO OBTAIN BETTER MONITORING DATA ON THE DIOXIN CONTAMINANT.

IN APRIL 1978, AS PART OF AN ONGOING PROGRAM TO REVIEW THE SAFETY OF PESTICIDES IN USE, EPA STARTED A REBUTTABLE PRESUMPTION AGAINST REGISTRATION REVIEW OF 2,4,5-T AND THE RELATED DIOXIN-CONTAMINATED HERBICIDE, SILVEX. EPA'S PRESUMPTION NOTICE SUMMARIZED EXTENSIVE TOXICITY TESTING CONDUCTED BY MANUFACTURERS, ACADEMIC RESEARCHERS, AND THE GOVERNMENT.

IN JUNE 1978, EPA RECEIVED A LETTER FROM EIGHT WOMEN LIVING IN THE VICINITY OF ALSEA, OREGON, WHO SAID THEY HAD EXPERIENCED 10 MISCARRIAGES SINCE 1973. THE WOMEN CLAIMED TO BE SURROUNDED BY FOREST LAND WHICH HAD BEEN SPRAYED FOR YEARS WITH HERBICIDES CONTAINING DIOXIN. IN JULY 1978, AS A RESULT OF THE WOMEN'S LETTER, EPA STAFF AND CONTRACT PERSONNEL BEGAN AN INVESTIGATION TO DETERMINE WHETHER THE REPORTED MISCARRIAGES HAD ANY POSSIBLE RELATIONSHIP TO THE 2,4,5-T SPRAYINGS. THIS INVESTIGATION, REFERRED TO AS ALSEA I, INVOLVED ADMINISTERING A QUESTIONNAIRE TO THE WOMEN WHICH ASKED ABOUT THEIR PREGNANCIES AND SOUGHT INFORMATION ON THEIR OWN AND FAMILY MEDICAL HISTORIES, DIET, AND HOUSEHOLD PESTICIDE USAGE. THE RESULTS WERE EVALUATED BY 10 EXPERTS, INCLUDING OBSTETRICIANS AND GYNECOLOGISTS. THE REVIEWERS CONCLUDED THAT THEY COULD NOT FIND A CAUSAL RELATIONSHIP BETWEEN FOREST HERBICIDE SPRAYING AND THE MISCARRIAGES. ON THE BASIS OF ALSEA I DATA, NO REGULATORY ACTION WAS TAKEN.

IN LATE SEPTEMBER 1978, EPA DECIDED THAT A BROADER-BASED EPIDEMIOLOGICAL STUDY ON THE POSSIBLE RELATIONSHIP BETWEEN THE SPRAYING OF 2,4,5-T AND MISCARRIAGES IN THE ALSEA AREA WAS NEEDED. THEREFORE, EPA, ALONG WITH SCIENTISTS ASSOCIATED WITH EPIDEMIOLOGICAL STUDIES PROGRAMS AT UNIVERSITIES IN COLORADO, FLORIDA, AND IDAHO, BEGAN A STUDY REFERRED TO AS ALSEA II. THE STUDY'S RESEARCHERS COLLECTED DATA ON 2,4,5-T USE AND ON LIVE BIRTHS AND HOSPITALIZED MISCARRIAGES IN THREE AREAS: (1) THE ALSEA STUDY AREA, (2) A CONTROL AREA WHICH, LIKE THE STUDY AREA, IS A RURAL REGION IN OREGON BUT IN WHICH LITTLE OR NO USE OF 2,4,5-T HAD OCCURRED, AND (3) AN URBAN AREA ENCOMPASSING TWO OREGON CITIES.

DURING JANUARY AND EARLY FEBRUARY 1979, EPA'S CONTRACTORS COMPLETED THEIR REPORTS AND SUBMITTED THEM TO EPA HEADQUARTERS. VARIOUS EPA STAFF REVIEWED AND EDITED THE REPORTS, AND EPA ISSUED A FINAL REPORT ON FEBRUARY 28, 1979. THE REPORT CONCLUDED THAT THERE HAD BEEN A STATISTICALLY SIGNIFICANT INCREASE IN MISCARRIAGES IN AREAS WHERE 2,4,5-T WAS USED AND THAT THIS INCREASE CORRELATED IN TIME WITH 2,4,5-T SPRAYING OPERATIONS. THE REPORT ADDED, HOWEVER, THAT THE ANALYSIS DID NOT PROVE THAT 2,4,5-T CAUSED THE INCREASE IN MISCARRIAGES.

ON FEBRUARY 28, 1979, THE SAME DATE THE ALSEA II REPORT WAS ISSUED, EPA ISSUED EMERGENCY ORDERS IMMEDIATELY SUSPENDING FORESTRY, RIGHTS-OF-WAY, AND PASTURE USES OF 2,4,5-T AND SILVEX. THE SILVEX ORDER ALSO SUSPENDED

HOME, GARDEN, AND SEVERAL OTHER USES. AS REQUIRED BY SECTION 6(c)(1) OF FIFRA, THE ORDERS ALSO ANNOUNCED EPA'S INTENTION TO CANCEL THE SUSPENDED USES OF THE TWO PESTICIDES.

ON MARCH 6, 1979, DOW CHEMICAL COMPANY AND OTHERS CHALLENGED THE EMERGENCY SUSPENSION ORDERS IN THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN. ON APRIL 12, 1979, THE COURT UPHELD THE ORDERS. ALSO, EPA SUSPENSION HEARINGS BEGAN ON APRIL 19, 1979, BUT WERE DISCONTINUED ON MAY 15, 1979, AFTER DOW CHEMICAL AND OTHER REGISTRANTS WITHDREW FROM THE HEARINGS.

ON DECEMBER 13, 1979, EPA ISSUED A NOTICE OF INTENT TO HOLD HEARINGS CONCERNING ALL NON-SUSPENDED USES OF PESTICIDE PRODUCTS CONTAINING 2,4,5-T AND SILVEX.

ON MARCH 14, 1980, EPA BEGAN CONSOLIDATED HEARINGS ON THE SUSPENDED AND NON-SUSPENDED USES OF THE PESTICIDES TO DETERMINE WHETHER TO CANCEL ALL USES OF 2,4,5-T AND SILVEX. EPA DECIDED TO CONSOLIDATE THE HEARINGS TO SAVE TIME AND ALLOW FOR A MORE COMPREHENSIVE AND EFFICIENT REVIEW OF THE RISKS AND BENEFITS OF THE PESTICIDES. EPA EXPECTS THE HEARINGS TO LAST ABOUT 2 YEARS.

GAO PRELIMINARY FINDINGS

TO DATE WE HAVE CONCENTRATED ON IDENTIFYING EPA PROCEDURES FOR REVIEWING AND VALIDATING EPIDEMIOLOGICAL STUDIES, SUCH AS ALSEA II, AND DETERMINING WHETHER EPA HAS FOLLOWED ITS PROCEDURES. WE HAVE ALSO EXAMINED EPA'S REASONS

FOR NOT USING ITS SCIENTIFIC ADVISORY PANEL TO EVALUATE EITHER ALSEA II OR THE OTHER SCIENTIFIC EVIDENCE APPEARING IN ITS FEBRUARY 28, 1979, NOTICES ANNOUNCING THE EMERGENCY SUSPENSIONS AND INTENT TO CANCEL CERTAIN USES OF 2,4,5-T AND SILVEX.

INFORMAL PROCEDURES NOT FOLLOWED

EPA HAS NO WRITTEN POLICY OR PROCEDURES ON WHETHER OR HOW TO REVIEW AND EVALUATE EITHER THE DESIGN OR THE RESULTS OF EPIDEMIOLOGICAL STUDIES, SUCH AS ALSEA II. EPA PESTICIDE OFFICIALS TOLD US, HOWEVER, THAT AS A MATTER OF PRACTICE THEY SOMETIMES OBTAIN PEER REVIEWS OF A STUDY'S DESIGN BEFORE INITIATING THE STUDY AND GENERALLY OBTAIN PEER REVIEWS OF STUDY RESULTS AFTER THEY ARE COMPLETED. THESE REVIEWS ARE GENERALLY PERFORMED BY TWO TO FOUR EPA SCIENTISTS OR CONSULTANTS, WHO ARE CONSIDERED EXPERTS ON THE SUBJECT MATTER BUT WHO HAVE NOT BEEN INVOLVED IN THE PARTICULAR PROJECT BEING REVIEWED. THE EPA PESTICIDE BRANCH RESPONSIBLE FOR OVERSEEING ALSEA II AND SIMILAR STUDIES HAS A LIST OF CONSULTANTS WHO, AMONG OTHER THINGS, PERFORM PEER REVIEWS FOR THE BRANCH.

EPA DID NOT OBTAIN PEER REVIEWS OF THE ALSEA II STUDY DESIGN. IN LATE SEPTEMBER OR EARLY OCTOBER 1978, EPA OFFICIALS DECIDED THAT THEY WANTED THE STUDY COMPLETED BY ABOUT MARCH 1, 1979, THE START OF THE 2,4,5-T SPRAYING SEASON. ACCORDING TO THE OFFICIALS, THIS TIME CONSTRAINT PREVENTED THEM FROM OBTAINING PEER REVIEWS.

CONCERNING PEER REVIEWS OF THE STUDY'S RESULTS, EPA HAS LITTLE DOCUMENTATION SHOWING WHAT OCCURRED. EPA PESTICIDE OFFICIALS SAID THAT THEY TRIED UNSUCCESSFULLY TO HAVE OUTSIDE SCIENTISTS PEER REVIEW THE STUDY RESULTS. THE EPA OFFICIAL RESPONSIBLE FOR OBTAINING THESE PEER REVIEWS TOLD US HE CALLED APPROXIMATELY 10 TO 13 SCIENTISTS ABOUT 30 DAYS BEFORE THE FEBRUARY 28, 1979, SUSPENSION ORDERS. TO THE BEST OF HIS RECOLLECTION NONE OF THE SCIENTISTS WERE AVAILABLE TO PEER REVIEW THE STUDY WITHIN EPA'S 30-DAY DEADLINE. HE ADDED THAT HE DID NOT MAINTAIN A RECORD OF WHOM HE CONTACTED, PRECISELY WHEN HE CONTACTED THEM, OR WHAT THEIR INDIVIDUAL RESPONSES WERE. HOWEVER, AN EPA CONSULTANT--WHO IS A MEMBER OF THE SCIENTIFIC ADVISORY PANEL--AND SEVERAL EPA SCIENTISTS AND TECHNICAL STAFF PERSONS REVIEWED THE STUDY'S RESULTS.

USE OF THE SCIENTIFIC ADVISORY PANEL

FIFRA ESTABLISHED THE SEVEN-MEMBER SCIENTIFIC ADVISORY PANEL IN 1975 TO PROVIDE THE EPA ADMINISTRATOR WITH ADVICE ON THE IMPACT ACTIONS PROPOSED IN A NOTICE TO EITHER CANCEL A PESTICIDE OR TO HOLD A HEARING TO DETERMINE WHETHER A PESTICIDE SHOULD BE CANCELED WILL HAVE ON HEALTH AND THE ENVIRONMENT. THE ACT REQUIRES THAT AT LEAST 60 DAYS PRIOR TO SENDING SUCH A NOTICE TO THE REGISTRANT OR MAKING IT PUBLIC, THE ADMINISTRATOR GIVE THE PANEL A COPY. THE PANEL HAS 30 DAYS TO COMMENT ON THE NOTICE. HOWEVER, THE

ADMINISTRATOR CAN WAIVE THE REQUIREMENT FOR OBTAINING THE PANEL'S COMMENTS IF THE IMMEDIATE SUSPENSION OF A PESTICIDE'S REGISTRATION IS NECESSARY TO PREVENT AN IMMINENT HAZARD TO HUMAN HEALTH. THIS IS WHAT HAPPENED ON 2,4,5-T AND SILVEX.

IN ISSUING HIS FEBRUARY 28, 1979, SUSPENSION ORDERS AND NOTICES OF INTENT TO CANCEL 2,4,5-T AND SILVEX, THE ADMINISTRATOR STATED THAT HE NEEDED TO IMMEDIATELY SUSPEND THE TWO PESTICIDES TO PREVENT AN IMMINENT HAZARD TO HUMAN HEALTH. ACCORDINGLY, HE WAIVED THE REQUIREMENT FOR THE PANEL'S REVIEW.

EPA DID NOT SUBSEQUENTLY ASK THE PANEL TO REVIEW AND COMMENT ON THE FEBRUARY 28, 1979, NOTICES. EPA'S OFFICE OF GENERAL COUNSEL BELIEVES THAT THE DESIGN OF THE CANCELLATION AND SUSPENSION PROVISIONS OF THE ACT ESTABLISHES THAT THE WAIVER OF THE PANEL'S REVIEW, ONCE INVOKED, IS INTENDED TO BE PERMANENT. EPA FURTHER BELIEVES THAT THE STATUTORY PURPOSE DISCLOSED BY THE ACT'S LEGISLATIVE HISTORY INDICATES THAT THE PANEL'S REVIEW WAS INTENDED TO PROVIDE PREDECISIONAL SCIENTIFIC GUIDANCE ON THE QUESTION OF WHETHER A PESTICIDE POSES A THREAT OF UNREASONABLE ADVERSE EFFECTS TO HUMAN HEALTH AND THE ENVIRONMENT.

AT THIS POINT, WE DO NOT QUESTION EPA'S INTERPRETATION OF THE LAW. HOWEVER, BASED ON OUR PRELIMINARY REVIEW OF THE EVENTS LEADING TO THE FEBRUARY 28, 1979, SUSPENSIONS,

WE ARE CONCERNED THAT THERE APPARENTLY WAS LITTLE INDEPENDENT SCIENTIFIC EVALUATION OF IMPORTANT EVIDENCE EPA RELIED ON WHEN DECIDING TO SUSPEND THE MAJOR USES OF THE TWO PESTICIDES.

OUR CONCERN FOR INDEPENDENT SCIENTIFIC ADVICE ON IMPORTANT REGULATORY ACTIONS IS NOT NEW. IN A SEPTEMBER 21, 1979, REPORT TO THE CONGRESS (CED-79-115) ON IMPROVING THE SCIENTIFIC AND TECHNICAL INFORMATION AVAILABLE TO EPA IN ITS DECISIONMAKING PROCESS, WE RECOMMENDED THAT EPA MAKE MORE USE OF ANOTHER EPA ADVISORY GROUP--THE SCIENCE ADVISORY BOARD. THE BOARD, UNLIKE THE PANEL WHICH DEALS ONLY IN PESTICIDE MATTERS, CAN BE REQUESTED BY THE ADMINISTRATOR, TO PROVIDE SCIENTIFIC AND TECHNICAL ADVICE ON ANY IMPORTANT ENVIRONMENTAL MATTER. WE CONCLUDED THAT THE BOARD, MANDATED BY THE ENVIRONMENTAL RESEARCH, DEVELOPMENT, AND DEMONSTRATION AUTHORIZATION ACT OF 1978, COULD PROVIDE VALUABLE INPUT INTO EPA'S DECISIONMAKING PROCESS ON MAJOR ACTIONS DEALING WITH SCIENTIFIC AND TECHNICAL INFORMATION. EPA GENERALLY AGREED WITH US.

SIMILARLY, WE BELIEVE THAT EPA SHOULD STRIVE TO MAKE MORE USE OF THE SCIENTIFIC ADVISORY PANEL ON IMPORTANT PESTICIDE REGULATORY ACTIONS. THEREFORE, AT THIS POINT IN OUR REVIEW, IT SEEMS TO US THAT AN AMENDMENT TO FIFRA MAY BE DESIRABLE TO EITHER (1) REQUIRE THE ADMINISTRATOR TO SEEK THE PANEL'S ADVICE BEFORE ISSUING A FINAL SUSPENSION ORDER, OR (2) REQUIRE THE ADMINISTRATOR TO DEVELOP REGULATIONS TO SEEK

THE PANEL'S ADVICE BEFORE ISSUING A FINAL SUSPENSION ORDER. WE WISH TO STRESS THAT IT IS NOT OUR INTENT TO DELAY THE ADMINISTRATOR WHEN HE HAS DECIDED THAT AN IMMINENT HAZARD EXISTS. IF, BECAUSE OF IMMINENT HAZARD, THE ADMINISTRATOR DOES NOT HAVE TIME TO SUBMIT A NOTICE OF INTENT TO SUSPEND OR A SUSPENSION ORDER TO THE PANEL BEFORE ISSUANCE, THE ADMINISTRATOR SHOULD SUBMIT THE NOTICE OR THE ORDER TO THE PANEL AT THE TIME OF ISSUANCE.

BECAUSE OF TIME CONSTRAINTS WE WERE NOT ABLE TO OBTAIN EPA'S VIEWS ON THESE MATTERS. WE BELIEVE, HOWEVER, THAT THIS AMENDMENT SHOULD IMPROVE THE DECISIONMAKING PROCESS BECAUSE IT WILL GIVE THE PANEL AN OPPORTUNITY TO COMMENT BEFORE THE ADMINISTRATOR RENDERS A FINAL SUSPENSION ORDER FOLLOWING AN EXPEDITED HEARING.

MR. CHAIRMAN, THIS CONCLUDES MY PREPARED STATEMENT. WE WILL BE GLAD TO RESPOND TO ANY QUESTIONS YOU MAY HAVE.