DOCUMENT RESUME

05119 - [B0485396]

Federal Efforts To Regulate Pesticide Residues in Food. February 14, 1978. 12 pp.

Testimony before the House Committee on Interstate and Foreign Commerce: Oversight and Investigations Subcommittee; by Henry Eschwege, Director, Community and Economic Development Div.

Contact: Community and Economic Development Div.
Organization Concerned: Environmental Protection Agency; Food and Drug Administration.
Congressional Relevance: House Committee on Interstate and Foreign Commerce: Oversight and Investigations Subcommittee.
Authority: Federal Food, Drug, and Cosmetic Act of 1938, as amended. Federal Insecticide, Fungicide, and Rodenticide Act of 1947, as amended.

The Environmental Protection Agency (EPA) is responsible for establishing all tolerances for pesticide residues on the basis of data submitted by petitioners concerning the nature, level, and toxicity of the residue. The Food and Drug Administration (FDA) is responsible for enforcing tolerances and accomplishes this by testing food samples to determine if residues exceed tolerance limits. The American public has not been adequately protected from potential hazards of pesticide use because of inadequate efforts to implement existing Federal laws. EPA established many tolerances without sufficient test data to determine the level of pesticide residue that would likely remain on a crop after treatment or the potential of the pesticide to cause cancers, birth defects, gene mutations, or reproductive difficulties. EPA did not always comply with its own procedures for limiting aggregate tolerances and registered pesticides for use on food crops without setting associated tolerances. FDA generally did not test food for over 75% of the pesticide residues for which tolerances had been established. A followup review of EPA and FDA actions indicated that little progress has been made. Data gaps still exist. Residues of 195 pesticides for which tolerances have been established are seldom, if ever, monitored in the food supply, and 21 pesticides suspected of causing cancer have 661 individual tolerances that will not be monitored by FDA's most frequently used test. (RRS)

5396

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

FOR RELEASE ON DELIVERY
EXPECTED AT 10 A.M. EST
TUESDAY, FEBRUARY 14, 1978

STATEMENT OF
HENRY ESCHWEGE, DIRECTOR
COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

ON

FEDERAL EFFORTS TO REGULATE
PESTICIDE RESIDUES IN FOOD

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

WE APPEAR BEFORE YOU TODAY TO DISCUSS OUR REPORT TO THE CONGRESS DATED DECEMBER 4, 1975, ENTITLED "FEDERAL PESTICIDE REGISTRATION PROGRAM: IS IT PROTECTING THE PUBLIC AND THE ENVIRONMENT ADEQUATELY FROM PESTICIDE HAZARDS?". IN RESPONSE TO YOUR REQUEST WE HAVE COMPLETED A FOLLOWUP STUDY TO DETERMINE WHAT ACTIONS THE ENVIRONMENTAL PROTECTION AGENCY (EPA) AND THE FOOD AND DRUG ADMINISTRATION (FDA) HAVE TAKEN ON OUR RECOMMENDATIONS ON REGULATING PESTICIDE RESIDUES IN FOOD.

BASIC LEGAL AUTHORITIES FOR REGULATING PESTICIDES ARE (1) THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT OF 1947, AS AMENDED, AND (2) THE FEDERAL FOOD, DRUG AND COSMETIC ACT OF 1938, AS AMENDED. AUTHORITY FOR ADMINISTERING THE 1947 ACT AND CERTAIN SECTIONS OF THE EARLIER ACT WERE TRANSFERRED FROM THE DEPARTMENT OF AGRICULTURE AND FROM FDA ALONG WITH THE RESPONSIBLE ORGANIZATIONAL ELEMENTS TO EPA ON DECEMBER 2, 1970, PURSUANT TO THE REORGANIZATION PLAN WHICH ESTABLISHED EPA.

PESTICIDE TOLERANCES

PESTICIDES USED ON FOOD AND FEED CROPS INCLUDE INSECTICIDES, HERBICIDES, FUNGICIDES, AND PLANT REGULATORS. IF A PESTICIDE APPLIED TO A GROWING CROP REMAINS IN OR ON FOOD OR FEED, A TOLERANCE OR MAXIMUM ALLOWABLE PESTICIDE RESIDUE IS REQUIRED TO BE ESTABLISHED AT A LEVEL WHICH WILL NOT HARM CONSUMERS. EPA'S OFFICE OF PESTICIDE PROGRAMS ESTABLISHES ALL TOLERANCES FOR PESTICIDE RESIDUES ON THE BASIS OF DATA SUBMITTED BY THE PETITIONER AS TO THE NATURE, LEVEL, AND TOXICITY OF THE RESIDUE.

ANY PESTICIDE RESIDUE ON FOOD IS CONSIDERED UNSAFE UNLESS A TOLERANCE HAS BEEN ESTABLISHED AND THE AMOUNT OF RESIDUE REMAINING IS WITHIN THE LIMITS OF THAT TOLERANCE. A PERMANENT TOLERANCE IS TO BE ESTABLISHED ONLY AFTER EPA IS SATISFIED THAT THE DATA SUBMITTED BY THE PETITIONER IS ADEQUATE TO SUPPORT THE SAFETY OF THE PROPOSED TOLERANCE. IN SOME CASES, AN EXEMPTION FROM THE REQUIREMENT FOR A TOLERANCE MAY BE GRANTED.

FDA IS RESPONSIBLE FOR ENFORCING TOLERANCES AND ACCOMPLISHES THIS BY TESTING SAMPLES OF FOOD TO DETERMINE IF RESIDUES EXCEEDING TOLERANCE LIMITS REMAIN. ANY FOOD PRODUCT CONTAINING RESIDUES OF A PESTICIDE FOR WHICH A TOLERANCE HAS NOT BEEN ESTABLISHED OR CONTAINING RESIDUES IN EXCESS OF ESTABLISHED TOLERANCES IS CONSIDERED ADULTERATED AND IS PROHIBITED FROM INTERSTATE COMMERCE. FDA CAN REMOVE SUCH PRODUCTS FROM INTERSTATE COMMERCE AND IMPOSE PENALTIES ON VIOLATORS.

IN OUR REPORT WE CONCLUDED THAT THE AMERICAN PUBLIC HAD NOT BEEN ADEQUATELY PROTECTED FROM THE POTENTIAL HAZARDS OF PESTICIDE USE BECAUSE OF INADEQUATE EFFORTS TO IMPLEMENT EXISTING FEDERAL LAWS. THIS CONCLUSION IN PART WAS BASED ON OUR FINDINGS THAT

—EPA ESTABLISHED MANY TOLERANCES WITHOUT SUFFICIENT TEST DATA TO DETERMINE (1) THE LEVEL OF A PESTICIDE RESIDUE THAT WOULD LIKELY REMAIN ON A CROP AFTER TREATMENT, AND OR (2) THE POTENTIAL OF THE PESTICIDE TO CAUSE CANCERS AND OTHER TUMORS, BIRTH DEFECTS, PERMANENT GENE MUTATIONS, OR REPRODUCTIVE DIFFICULTIES.

—EPA DID NOT ALWAYS COMPLY WITH ITS PROCEDURES FOR LIMITING AGGREGATE TOLERANCES TO THE ACCEPTABLE DAILY INTAKE OF THE PESTICIDE.

—EPA REGISTERED PESTICIDES FOR USE ON FOOD OR FEED CROPS WITHOUT SETTING ASSOCIATED TOLERANCES.

—FDA GENERALLY DID NOT TEST FOOD FOR OVER 75 PERCENT OF THE PESTICIDE RESIDUES FOR WHICH PESTICIDE TOLERANCES HAD BEEN ESTABLISHED.

OUR FOLLOWUP REVIEW OF ACTIONS TAKEN BY EPA AND FDA TO IMPLEMENT OUR RECOMMENDATIONS SHOWS THAT LITTLE PROGRESS HAS BEEN MADE. FOR EXAMPLE:

—DATA GAPS STILL EXIST AND REGISTRANTS HAVE NOT BEEN OFFICIALLY NOTIFIED TO SUBMIT THE MISSING DATA BY SPECIFIED DATES.

—RESIDUES OF 195 OF THE 268 PESTICIDES FOR WHICH TOLERANCES HAVE BEEN ESTABLISHED ARE SELDOM IF EVER MONITORED IN THE FOOD SUPPLY AND 21 PESTICIDES SUSPECTED OF CAUSING CANCER OR OTHER TUMORS HAVE 661 INDIVIDUAL TOLERANCES THAT WILL NOT BE MONITORED BY FDA'S MOST FREQUENTLY USED MULTIRESIDUE TEST. THESE TOLERANCES AFFECT A MAJOR PORTION OF OUR FOOD SUPPLY.

THESE DEFICIENCIES AND THE NEED FOR CORRECTIVE ACTIONS BY EPA AND FDA ARE THE SUBJECT OF OUR TESTIMONY TODAY.

TOLERANCES BASED ON INADEQUATE SAFETY DATA

ALTHOUGH REQUIRED BY EPA REGULATIONS, MANY SAFETY TESTS DESIGNED TO DETERMINE THE POTENTIAL OF PESTICIDES TO CAUSE CANCER AND OTHER TUMORS, BIRTH DEFECTS, PERMANENT GENE MUTATIONS, AND REPRODUCTIVE DIFFICULTIES HAVE NOT BEEN COMPLETED TO SUPPORT FOOD RESIDUE TOLERANCES ESTABLISHED BY EPA OR ITS PREDECESSOR. THESE TESTS ARE NECESSARY TO INSURE THAT TOLERANCES ARE SET AT LEVELS WHICH WILL NOT ADVERSELY AFFECT THOSE EATING FOOD TREATED WITH THE PESTICIDE OR EATING MEAT OR ANIMAL PRODUCTS SUCH AS MILK AND EGGS FROM ANIMALS THAT CONSUME PESTICIDE-TREATED FEED.

EVEN THOUGH MANY PESTICIDE TOLERANCES IN USE TODAY WERE ESTABLISHED BEFORE SEVERAL IMPORTANT SAFETY TESTS WERE REQUIRED, EPA DOES NOT REEVALUATE THESE TOLERANCES IN TERMS OF THE NEW DATA REQUIREMENTS TO INSURE THAT THEY PROVIDE ADEQUATE PROTECTION.

OUR 1975 REPORT NOTED THAT 36 RANDOMLY SELECTED PESTICIDE CHEMICALS WHERE TOLERANCES HAD BEEN ESTABLISHED LACKED THE SAFETY DATA THAT IS NOW REQUIRED. SEVEN OF THE CHEMICALS LACKED CANCER STUDIES, 7 LACKED REPRODUCTION STUDIES, 14 LACKED BIRTH DEFECT STUDIES, AND 23 LACKED MUTATION STUDIES. ALL OF THESE STUDIES HAVE BEEN REQUIRED SINCE 1972.

EVEN AFTER NEW STUDIES WERE REQUIRED, WE NOTED SEVERAL CASES WHERE TOLERANCES FOR ADDITIONAL USES OF A PREVIOUSLY REGISTERED PESTICIDE WERE GRANTED WITHOUT SUBMISSION OF SUCH DATA. FOR EXAMPLE, EPA GRANTED TOLERANCES FOR ADDITIONAL USES OF CARBOPHENOTHION AND CACODYLIC ACID AFTER BIRTH DEFECTS AND GENE MUTATION STUDIES WERE REQUIRED IN 1972 WITHOUT SUBMISSION OF THESE STUDIES. CACODYLIC ACID IS SUSPECTED OF CAUSING CANCER, GENE MUTATIONS, AND ADVERSE EFFECTS ON REPRODUCTION. IN ADDITION, EPA

HAD NOT SET A TOLERANCE FOR CARBOPHENOTHION RESIDUES IN MILK, EVEN THOUGH EPA WAS AWARE IN 1973 THAT ITS USE IN DAIRY CATTLE FEED WOULD RESULT IN RESIDUES IN MILK. MILK MAY CONSTITUTE THE ENTIRE DIET OF INFANTS WHO ARE MORE SUSCEPTIBLE TO THE ADVERSE EFFECTS OF PESTICIDES THAN ARE OTHERS IN THE POPULATION.

IN RESPONSE TO OUR RECOMMENDATIONS, EPA STATED THAT DATA GAPS SUPPORTING TOLERANCES WOULD BE IDENTIFIED AND REGISTRANTS WOULD BE PROVIDED A REASONABLE PERIOD TO DEVELOP THE DATA.

EPA ACTIONS

EPA HAS INFORMED US THAT IN APRIL 1977 ITS SCIENCE ADVISORY BOARD WAS ASKED TO STUDY THE SCIENTIFIC FOUNDATIONS OF THE ENTIRE TOLERANCE SETTING PROGRAM. EPA SAID IT WAS HOPEFUL THAT THE BOARD'S REPORT WILL PROVIDE (1) THE GROUNDWORK FOR ANY NECESSARY OVERHAUL OF THE TOLERANCE SETTING SYSTEM, AND (2) AN ORDERLY WAY TO REVIEW EXISTING TOLERANCES AND REVOKE OR MODIFY THEM APPROPRIATELY.

EPA TOLD US THAT WHILE NO FORMAL PROCESS NOW EXISTS FOR REVIEWING PREVIOUSLY ESTABLISHED TOLERANCES ON A LARGE SCALE, THERE IS A PROGRAM FOR REVIEWING THE HEALTH AND SAFETY OF PESTICIDES USED ON FOODS CALLED THE REBUTTABLE PRESUMPTION AGAINST REGISTRATION (RPAR) PROCESS WHICH WAS IMPLEMENTED AFTER ISSUANCE OF THE GAO REPORT IN DECEMBER 1975. THIS PROCESS IS INTENDED TO PROVIDE A DETAILED REVIEW OF THE SCIENTIFIC DATA SUPPORTING REGISTRATION OF PESTICIDES WITH POTENTIAL ADVERSE EFFECTS EXCEEDING ESTABLISHED RISK CRITERIA; THOSE THAT ARE FOUND TO POSE AN UNREASONABLE RISK WILL BE SUBJECT TO EPA CANCELLATION ACTION. AS OF JANUARY 1978 THERE WERE 19 PESTICIDES THAT WERE BEING REVIEWED UNDER THIS PROCESS AND ANOTHER 60 THAT MAY BE REVIEWED. WHILE THIS PROGRAM IS A LAUDABLE EFFORT, IT IS

DIRECTED TOWARD THOSE PESTICIDES WHICH HAVE ALREADY BEEN IMPLICATED AS HAVING POTENTIAL ADVERSE HUMAN HEALTH EFFECTS. ONLY 7 OF THE 36 CHEMICALS DISCUSSED IN OUR 1975 REPORT AS LACKING SAFETY STUDIES WILL BE COVERED BY THE PROCESS.

EPA PUBLISHED IN THE FEDERAL REGISTER IN FEBRUARY 1976, A LISTING OF 442 REGISTERED PESTICIDES WHICH LACKED STUDIES THAT WOULD REQUIRE OVER 2 YEARS TO COMPLETE. EPA HAS NOT YET DIRECTED REGISTRANTS TO COMPLETE THESE STUDIES, AND ALTHOUGH 2 YEARS HAVE ELAPSED SINCE OUR REPORT WAS ISSUED, LITTLE PROGRESS HAS BEEN ACHIEVED IN OVERHAULING THE TOLERANCE SETTING SYSTEM.

TOLERANCES BASED ON INADEQUATE RESIDUE DATA

TOLERANCES WERE ESTABLISHED IN 1955 FOR 28 PESTICIDES USED ON ABOUT 50 CROPS. WE LOOKED AT 10 COMMON CROPS SUCH AS APPLES, BEANS, AND PEACHES FOR WHICH 143 TOLERANCES HAD BEEN ESTABLISHED; RESIDUE DATA WAS NOT AVAILABLE FOR 91 OF THE TOLERANCES. OF THE REMAINING 52 TOLERANCES ESTABLISHED, ONLY 6 ACCURATELY REFLECTED AVAILABLE RESIDUE DATA, 27 WERE SET ABOVE AND 19 WERE SET BELOW KNOWN RESIDUES REMAINING ON THE CROP. TOLERANCES SET AT ARTIFICIALLY HIGH LEVELS MAY SUBJECT THE PUBLIC TO GREATER THAN NECESSARY PESTICIDE RESIDUES IN FOOD. TOLERANCES SET BELOW THE RESIDUE LEVEL EXPECTED FROM PROPER APPLICATION OF THE PESTICIDE MAY RESULT IN EXCESSIVE RESIDUES WHICH WOULD RENDER THE FOOD ADULTERATED, AND SUBJECT TO FDA REMOVAL FROM INTERSTATE COMMERCE.

EPA ACTIONS

EPA STILL HAS NOT REQUESTED RESIDUE DATA EXCEPT FOR THOSE TOLERANCES TO BE EXAMINED UNDER THE REBUTTABLE PRESUMPTION AGAINST REGISTRATION PROCESS. EPA INFORMED US THAT IT WILL REVIEW THE ADEQUACY OF ESTABLISHED TOLERANCES

AS GENERIC STANDARDS ARE DEVELOPED FOR ACTIVE INGREDIENT PESTICIDE CHEMICALS. GENERIC STANDARDS ARE AN INTEGRAL PART OF THE REREGISTRATION OF ALL PESTICIDES MANDATED BY THE LAW. EPA STATED IN RECENT CONGRESSIONAL TESTIMONY THAT REREGISTRATION WILL TAKE BETWEEN 10 AND 15 YEARS.

ACCEPTABLE DAILY INTAKE OF PESTICIDES NOT CONSIDERED

EPA DETERMINES THE ACCEPTABLE DAILY INTAKE FOR RESIDUES OF EACH PESTICIDE WHICH MAY BE PRESENT ON FOOD. ACCEPTABLE DAILY INTAKE FOR MAN IS USUALLY 1 PERCENT OF THE PESTICIDE CONCENTRATION FOUND TO HAVE NO TOXIC EFFECT IN THE MOST SENSITIVE ANIMAL SPECIES TESTED.

EPA DETERMINES THE TOTAL POSSIBLE EXPOSURE TO PESTICIDE RESIDUES THAT COULD BE PRESENT IN EACH FOOD COMMODITY IN THE AVERAGE DIET OF AN AMERICAN MALE. THE RESIDUES FROM EACH FOOD COMMODITY ARE THEN TOTALED AND COMPARED TO THE ACCEPTABLE DAILY INTAKE. IF THE TOTAL RESIDUES FOR A PESTICIDE FROM ALL COMMODITIES ARE BELOW THE ACCEPTABLE DAILY INTAKE FOR THAT PESTICIDE, THEN THE TOLERANCES ESTABLISHED ARE CONSIDERED TO BE SAFE.

WE FOUND SOME INSTANCES WHERE THE TOTAL PESTICIDE EXPOSURE EXCEEDED ACCEPTABLE DAILY INTAKE. FOR EXAMPLE, EPA HAD SET TOLERANCES FOR TOXAPHENE IN OVER 50 AGRICULTURAL COMMODITIES AND FOR PARATHION IN ABOUT 70 COMMODITIES. IN SETTING THESE TOLERANCES EPA DID NOT CONFORM TO ITS STATED PROCEDURES FOR COMPUTING AND LIMITING TOTAL PUBLIC EXPOSURE TO THESE PESTICIDES IN FOOD--POTENTIAL PUBLIC EXPOSURE TO TOXAPHENE WAS ALMOST FOUR TIMES AND TO PARATHION WAS ALMOST TWICE THE ACCEPTABLE DAILY INTAKE. WE RECOMMENDED THAT EPA UNIFORMLY APPLY ITS STATED METHODOLOGY, LIMITING PUBLIC EXPOSURE TO PESTICIDE RESIDUES IN FOOD.

EPA ACTIONS

IN JANUARY 1978 EPA TOLD US THAT ADDRESSING THE APPROPRIATENESS OF ACCEPTABLE DAILY INTAKE IN THE TOLERANCE-SETTING PROCESS WAS ONE OF THOSE AREAS REFERRED TO EPA'S SCIENCE ADVISORY BOARD IN APRIL 1977. IN DECEMBER 1977 THE BOARD HAD SUBMITTED A PLAN TO EPA FOR CARRYING OUT ITS REVIEW OF THE TOLERANCE-SETTING PROCESS. NO DATE HAS BEEN SET FOR COMPLETING THE PROJECT.

PESTICIDES MARKETED WITHOUT A TOLERANCE

EPA HAS PERMITTED THE REGISTRATION OF PESTICIDES RESULTING IN RESIDUES ON FOOD WITHOUT ESTABLISHING RELATED TOLERANCES. FOR EXAMPLE, SOME USES OF CHLORDANE RESULT IN RESIDUES IN MILK; HOWEVER, TOLERANCES FOR SUCH RESIDUES HAVE NOT BEEN SET. THUS, USING THE PRODUCT ACCORDING TO LABEL DIRECTIONS COULD ADULTERATE MILK.

WE HAD REPORTED THAT IN JUNE 1972 EPA'S TOXICOLOGY BRANCH HAD STRONGLY OBJECTED TO THE CONTINUED REGISTRATION OF CHLORDANE, ENDRIN, HEPTACHLOR, AND SILVEX FOR CERTAIN USES BECAUSE AVAILABLE TOXICITY DATA DID NOT SUPPORT THE PROPOSED TOLERANCES OR BECAUSE RESIDUE DATA WAS INSUFFICIENT TO DETERMINE APPROPRIATE TOLERANCES. HOWEVER, THE OFFICE OF PESTICIDE PROGRAMS OVERRULED THE TOXICOLOGY BRANCH, STATING THAT ABSENCE OF A TOLERANCE DID NOT PRECLUDE REGISTRATION OF THE USES AND THAT THERE SEEMED TO BE ONLY A WEAK CASE FOR CANCELLATION.

EPA ACTION

AS OF JANUARY 1978 EPA HAD NOT SET TOLERANCES FOR ANY OF THE QUESTIONED USES OF CHLORDANE, ENDRIN, HEPTACHLOR, AND SILVEX—ALL OF WHICH ARE SUSPECTED OF CAUSING CANCER OR OTHER TUMORS. THE MANUFACTURE

OF CHLORDANE AND HEPTACHLOR WAS SUSPENDED ON JULY 30, 1975, BUT AS YET THE REGISTRATIONS HAVE NOT BEEN CANCELED. FURTHER, ENDRIN IS UNDERGOING EPA SCIENTIFIC SCRUTINY TO DETERMINE WHETHER CANCELLATION ACTION IS WARRANTED AND SILVEX IS BEING CONSIDERED FOR SIMILAR SCRUTINY.

QUESTIONABLE INTERIM TOLERANCES ESTABLISHED

EPA ESTABLISHED INTERIM TOLERANCES FOR USE OF SOME PESTICIDE WHILE THE REVIEW OF THE PERMANENT TOLERANCE PETITION WAS IN PROGRESS. INTERIM TOLERANCES WERE USUALLY ESTABLISHED WHEN (1) QUESTIONS OF SAFETY EXISTED, (2) INADEQUATE DATA WAS PROVIDED ON RESIDUE LEVELS, OR (3) PETITIONERS SUBMITTED NO DATA TO SUPPORT THE SAFETY OF THE PROPOSED USES. GUIDELINES HAD NOT BEEN PREPARED COVERING INTERIM TOLERANCES. ALTHOUGH ESTABLISHING AN INTERIM TOLERANCE ALLOWS THE USE OF A PESTICIDE WITHOUT THE TREATED FOOD PRODUCT BEING CONSIDERED ADULTERATED, IT BY NO MEANS INSURES THAT SUCH RESIDUES CAN BE CONSUMED SAFELY.

WE RECOMMENDED THAT EPA REVIEW THE JUSTIFICATION FOR INTERIM TOLERANCES IN LIGHT OF ITS RESPONSIBILITY TO PROTECT THE PUBLIC FROM PESTICIDE HAZARDS, DEVELOP GUIDELINES, AND IF NEEDED, PREPARE LEGISLATION COVERING THEIR USE. WE ALSO RECOMMENDED THAT THE STATUS OF ALL EXISTING INTERIM TOLERANCES SHOULD BE REVIEWED FOR CONFORMITY WITH THE GUIDELINES.

EPA ACTIONS

IN OUR REPORT WE CITED SIX EXAMPLES OF INTERIM TOLERANCES ESTABLISHED BETWEEN 1967 AND 1974 WHICH WERE NOT SUPPORTED BY ADEQUATE SAFETY OR RESIDUE DATA. AS OF JANUARY 1978, ONE OF THE SIX HAD EXPIRED, TWO WERE CONVERTED TO PERMANENT TOLERANCES, AND THREE WERE STILL IN FORCE AS INTERIM TOLERANCES. AN EPA OFFICIAL TOLD US THAT THE THREE HAD NOT BEEN UPGRADED TO FULL TOLERANCE STATUS BECAUSE THE DATA GAPS HAD NOT BEEN FILLED BY PETITIONERS. THE THREE

PESTICIDES WITH INTERIM TOLERANCES ARE ALL UNDER SCIENTIFIC SCRUTINY IN EPA'S EVALUATION PROCESS TO DETERMINE IF CONTINUED REGISTRATION OF THE PESTICIDES IS WARRANTED.

WE ALSO NOTED THAT THERE ARE 18 ADDITIONAL INTERIM TOLERANCES WHICH ARE STILL IN EFFECT; 2 ARE FOR CHEMICALS THAT ARE BEING CANCELLED AND 6 ARE FOR CHEMICALS EITHER BEING SUBJECTED TO, OR CONSIDERED FOR, THE EVALUATION PROCESS. THESE TOLERANCES HAVE NOT BEEN CONVERTED TO PERMANENT TOLERANCES BECAUSE RESIDUE OR SAFETY DATA HAS NOT YET BEEN PROVIDED BY THE REGISTRANT.

WE NOTED FURTHER THAT ALTHOUGH THEY ARE NOT CALLED INTERIM TOLERANCES, EPA CONTINUES TO SET SOME TOLERANCES WITHOUT REQUIRING SAFETY DATA. FOR EXAMPLE, TOLERANCES HAD BEEN ESTABLISHED DURING 1976 AND 1977 FOR PESTICIDES WITHOUT STUDIES AS TO THEIR POTENTIAL FOR CAUSING CANCERS OR OTHER TUMORS, OR BIRTH DEFECTS.

FDA NOT TESTING FOR MOST PESTICIDE RESIDUES IN FOOD

IN 1975 WE REPORTED THAT FDA WAS NOT TESTING FOR RESIDUES IN FOOD FOR 179 OF THE 253 PESTICIDES WHICH HAD TOLERANCES. FDA USED A MULTIRESIDUE TEST WHICH IS CAPABLE OF DETECTING 54 PARENT-COMPOUND PESTICIDE CHEMICALS--PRIMARILY INSECTICIDES--AND ABOUT 90 OF THEIR METABOLITES IN FOOD. FDA TOLD US THAT SUITABLE MULTIRESIDUE METHODS WERE NOT AVAILABLE FOR MOST REGISTERED PESTICIDES, AND AS SUCH, THESE PESTICIDES WERE NOT ROUTINELY INCLUDED IN FDA'S SURVEILLANCE PROGRAM.

FDA'S MULTIRESIDUE TESTING CAPABILITY FOR OTHER TYPES OF PESTICIDES WAS EXTREMELY LIMITED. FOR EXAMPLE, 63 OF 72 HERBICIDES AND THE MOST WIDELY USED FUNGICIDES HAVING TOLERANCES WERE NOT DETECTABLE WITH FDA'S MULTIRESIDUE TEST. THIS IS ESPECIALLY SIGNIFICANT BECAUSE HERBICIDE USE IS GREATER THAN INSECTICIDE USE AND BECAUSE A DECOMPOSITION PRODUCT OF THE FUNGICIDES IS

SUSPECTED OF CAUSING CANCER. THE IMPACT ON THE PUBLIC HEALTH RESULTING FROM EXPOSURE T THESE PESTICIDES IS UNKNOWN.

METHODOLOGIES DO EXIST FOR DETECTING RESIDUES OF PESTICIDES HAVING TOLERANCES. HOWEVER, MOST OF THESE METHODS ARE SINGLE RESIDUE METHODS THAT DETECT ONLY ONE PESTICIDE PER ANALYSIS AS OPPOSED TO MULTIRESIDUE METHODS WHICH DETECT MANY PESTICIDES IN ONE ANALYSIS. PUBLIC EXPOSURE TO THE MANY PESTICIDES DETECTABLE ONLY BY SINGLE RESIDUE METHODS IS LARGELY UNKNOWN BECAUSE FDA HAS RARELY USED THESE METHODS.

FDA DID NOT CONCUR WITH OUR RECOMMENDATION TO EXPAND ITS SURVEILLANCE PROGRAM BECAUSE FDA BELIEVED THAT OVER A PERIOD OF YEARS THE RESULTS OF ITS EXISTING PROGRAM HAD INDICATED THAT PESTICIDE LEVELS FOUND IN MOST RAW AGRICULTURAL COMMODITIES ARE GENERALLY WELL BELOW ESTABLISHED TOLERANCES--VIOLATIVE LEVELS OF PESTICIDE RESIDUES WERE FOUND IN ONLY ABOUT 3 PERCENT OF THE SAMPLES TESTED. FDA BELIEVED THAT IT SHOULD CONTINUE TO PLACE EMPHASIS ON MULTIRESIDUE TESTS RATHER THAN USING OTHER METHODS WHICH WOULD DETECT ONLY ONE PESTICIDE.

WE CONCLUDED THAT THE 3 PERCENT RATE OF VIOLATIVE SAMPLES FDA NOTED INDICATED THAT ILLEGAL RESIDUES DO OCCUR DESPITE EFFORTS TO THE CONTRARY. THIS OCCURENCE DEMONSTRATED TO US A NEED FOR FDA TO INITIATE A SYSTEMATIC PROCEDURE TO INSURE THAT ALL PESTICIDES WITH TOLERANCES ARE TESTED IN FDA'S SURVEILLANCE PROGRAM OVER A NUMBER OF YEARS.

FDA ACTIONS

IN OUR FOLLOW UP STUDY, WE FOUND THAT FOR THE MOST PART, FDA IS STILL USING THE SAME MULTIRESIDUE TEST PREVIOUSLY CITED. CURRENTLY THIS TEST WILL DETECT 73 OF THE 268 PESTICIDES THAT HAVE PERMANENT TOLERANCES FOR RESIDUES ON RAW AGRICULTURAL COMMODITIES. FDA HAS FIVE ADDITIONAL MULTIRESIDUE

METHODS WHICH WOULD ENABLE FDA TO DETECT 34 ADDITONAL PESTICIDES, OR A TOTAL OF 107 OF THE 268 PESTICIDES. HOWEVER, FDA WAS UNABLE TO PROVIDE DATA ON HOW MANY TIMES THE ADDITIONAL MULTIRESIDUE METHODS WERE USED. FDA SAID THAT THREE SPECIAL STUDIES TOTALING 540 SAMPLES WERE DONE IN FISCAL YEAR 1977 AND THAT TWO FDA REGIONS USED ONE OF THE ADDITIONAL MULTIRESIDUE METHODOLOGIES (IN LIEU OF THE COMMONLY USED METHOD) IN TESTING IMPORTED FRUIT AND VEGETABLES--THIS TOTALS LESS THAN 20 PERCENT OF THE 9,800 FOOD SAMPLES FDA EXPECTED TO TEST FOR RESIDUES IN FISCAL YEAR 1977. ANOTHER STUDY OF 564 FOOD SAMPLES WAS DONE OVER FISCAL YEARS 1977 AND 1978.

TO PLACE FDA'S RESIDUE TESTING IN PERSPECTIVE, WE DETERMINED THAT THE 268 PESTICIDE CHEMICALS WITH TOLERANCES CONTAINED 5,872 INDIVIDUAL TOLERANCES. OF THIS TOTAL, ONLY 2,240 (38 PERCENT) CAN BE DETECTED USING FDA'S MOST COMMONLY USED MULTIRESIDUE METHOD. ALSO, 940 OF THE 5,872 TOLERANCES ARE FOR CHEMICALS WHICH ARE SUSPECTED OF CAUSING CANCER OR OTHER TUMORS; 661 (70 PERCENT) ARE NOT DETECTED BY FDA'S MOST USED MULTIRESIDUE METHOD.

OUR FOLLOWUP OF OUR 1975 REPORT AGAIN LEADS US TO CONCLUDE THAT FDA'S RESIDUE TESTING PROGRAM SHOULD BE EXPANDED TO PROVIDE GREATER PESTICIDE RESIDUE TESTING COVERAGE, PARTICULARLY FOR THOSE CHEMICALS SUSPECTED OF CAUSING CANCER AND OTHER TUMORS.

— — — — —

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