

A REVIEW OF PCB'S IN THE GREAT LAKES AREA

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THIS PRESENTATION, TODAY, IS INTENDED TO BE AN UPDATING CONCERNING THE STATUS OF POLYCHLORINATED BIPHENYLS (PCB'S) PARTICULARLY IN RELATION TO LAKE MICHIGAN FISH. THE INFORMATION AND THE WORK DISCUSSED COME FROM MANY PEOPLE. SOME OF THE OTHER PARTICIPANTS IN THIS MEETING HAVE PLAYED A MAJOR ROLE IN DEVELOPING THIS MATERIAL AND WILL NO DOUBT RECOGNIZE THEIR OWN INPUT. I HOPE THAT THIS SUMMARY WILL FORM A REASONABLE BASIS FOR DETERMINING THE PROPER STEPS TO FOLLOW IN THE FUTURE, BOTH IN RELATION TO PCB'S AND ANY FUTURE SIMILAR DISCOVERIES.

THE POLYCHLORINATED BIPHENYLS (PCB'S) COMPRISE A FAMILY OF ORGANIC CHEMICALS OF QUITE REMARKABLE CHEMICAL AND PHYSICAL PROPERTIES. PCB'S ARE MANUFACTURED COMMERCIALY UNDER THE TRADENAME AROCLOR BY THE MONSANTO CHEMICAL COMPANY, THE SOLE MANUFACTURER IN THE UNITED STATES. THEY WERE FIRST PRODUCED COMMERCIALY IN 1929. THE CHLORINE CONTENT OF INDIVIDUAL USEFUL PRODUCTS VARIES FROM ABOUT 20-70% BY WEIGHT; THOSE UP TO ABOUT 54% ARE LIQUIDS AND THOSE ABOVE 54% ARE SOLIDS. THE PCB'S ARE EXTRA-ORDINARILY STABLE AND CHEMICALLY INERT; HAVE A HIGH DIELECTRIC CONSTANT AND A HIGH BOILING POINT; ARE NONFLAMMABLE AND VERY RESISTANT TO DECOMPOSITION BY HEAT.

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INDUSTRY RAPIDLY CAPITALIZED ON THE UNIQUE PROPERTIES OF PCB'S AND BEGAN USING THEM FOR A VARIETY OF PURPOSES: INSULATING FLUIDS IN ELECTRICAL TRANSFORMERS AND CAPACITORS, HEAT EXCHANGE FLUIDS, HYDRAULIC FLUIDS, PAINTS, PLASTICIZERS, PRINTING INKS, FIRE RETARDANTS, CARBONLESS COPY PAPER, AND NUMEROUS OTHER USES WHERE ELECTRICAL NON-CONDUCTANCE, NON-FLAMMABILITY AND HEAT RESISTANCE PROPERTIES ARE USEFUL.

THE PCB'S ARE HIGHLY PERSISTENT IN THE ENVIRONMENT; THEY RESIST BOTH CHEMICAL AND MICROBIOLOGICAL DEGRADATION. THUS, IN 1971, THE MANUFACTURER ANNOUNCED THAT PRODUCTS FOR USE ONLY IN CLOSED SYSTEMS SUCH AS ELECTRICAL TRANSFORMERS AND CAPACITORS WOULD BE SUPPLIED. ALL OTHERS WERE BEING DISCONTINUED BECAUSE OF THE POTENTIAL FOR ENVIRONMENTAL CONTAMINATION.

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WHILE PCB'S HAD BEEN WIDELY USED NOT ONLY IN THE U.S. BUT THROUGHOUT THE WORLD FOR ALMOST 40 YEARS, IT WAS NOT RECOGNIZED THAT THERE MIGHT BE AN ENVIRONMENTAL PROBLEM UNTIL SOREN JENSEN IDENTIFIED PCB'S IN BIRD TISSUE IN SWEDEN IN 1966. SOREN JENSEN REVEALED THAT THE PCB'S WERE DISPERSED WIDELY IN THE ENVIRONMENT, TO THE EXTENT THAT HE IDENTIFIED PCB IN PIKE (IN DIFFERENT PARTS OF SWEDEN), IN OTHER FISH AND IN AN EAGLE.

FURTHER ANALYSES FOR PCB WERE MADE IN EAGLE FEATHERS PRESERVED IN A MUSEUM, SOME OF THESE DATING BACK TO 1880 WITH NEGATIVE RESULTS, BUT PCB WAS FOUND IN FEATHERS WHICH WERE COLLECTED IN 1944. WITHIN THE SAME YEAR OF JENSEN'S OBSERVATION, WIDMARK, A COLLEAGUE OF HIS, REPORTED TO AN INTERNATIONAL COMMISSION STUDYING PESTICIDE ANALYSIS THAT A COMPOUND SIMILAR TO DDT IN IDENTIFICATION AND ANALYSIS, WHICH CONTAINED CHLORINE, CREATED A

PROBLEM IN ISOLATION AND IDENTIFICATION OF RESIDUES OF DDT. SINCE THAT TIME PCB HAS BEEN FOUND IN FISH, SEA BIRDS, PINE NEEDLES, RAIN-WATER (NOT DETECTED AS YET IN AIRBORNE PARTICULATES), HUMAN BODY FAT AND MOTHER'S MILK.

INITIALLY, THE CONCERN ABOUT THIS SYNTHETIC CHEMICAL IN TERMS OF HUMAN HEALTH, WAS LIMITED TO OCCUPATIONAL EXPOSURE, AT LEAST PRIOR TO 1966. SINCE THEN, BECAUSE OF THIS SERIES OF COMPOUNDS BEING TOO WIDELY DISTRIBUTED IN THE ENVIRONMENT AND PERHAPS BEING AS UBIQUITOUS AS DDT, THEIR POTENTIAL HAZARDS TO MARINE, AVIAN, AND MAMMALIAN SPECIES, INCLUDING MAN, ARE BEING EXPLORED. IN AN INVESTIGATION ON THE PEREGRINE FALCON (FAST DISAPPEARING BIRD OF PREY), RISEBROUGH ET AL (1968) SHOWED THE PRESENCE OF SOME UNKNOWN COMPOUNDS, ALONG WITH DDT AND DDE, IN THE EGGS OF A FALCON NEST WHICH DID NOT HATCH. THESE HITHERTO UNIDENTIFIED COMPOUNDS WERE LATER FOUND TO BE POLYCHLORINATED BIPHENYLS. IN THE NORTH AMERICAN PEREGRINE FALCON, PCB WAS FOUND AT THE LEVEL OF 1.980 PPM AND IN A WHITE TAILED EAGLE IN SWEDEN AT THE LEVEL OF 17,000 PPM. APPARENTLY, THE GREATER THE DISTANCE AWAY FROM INDUSTRIAL CENTERS THE MORE THE LEVEL OF PCB DECREASES FOR VARIOUS ORGANISMS.

VARIOUS SPECULATIONS HAVE BEEN ADVANCED AS TO THE ORIGIN OF THESE ENVIRONMENTAL POLLUTANTS, BUT APPARENTLY THESE COMPOUNDS, LIKE DDT, ARE CARRIED BY GLOBAL AIR CURRENTS FROM THE ARCTIC CIRCLE TO THE SOUTHERN HEMISPHERE. MORE STUDIES ARE NEEDED TO IDENTIFY THE ROUTES OF ENTRY OF PCB INTO THE ENVIRONMENT.

ONE IMPORTANT OBSERVATION IS THAT THE MORE LIGHTLY CHLORINATED PCB'S ARE SOMEWHAT LESS PERSISTENT AND ACCORDINGLY MORE READILY METABOLIZED AND EXCRETED; WHEREAS THE HIGHLY CHLORINATED COMPOUNDS ARE MORE PERSISTENT AND BY INFERENCE, NO DOUBT, LESS EASILY DEGRADED IN THE BODY. THERE IS LITTLE KNOWN ABOUT THE METABOLITES OF PCB.

SAX, IN HIS DESCRIPTION OF DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS, INCLUDES PCB AS A TOXIC AGENT AFFECTING HUMAN SKIN AND LIVER AT HIGH CONCENTRATIONS. HE DESCRIBES THE LESION PRODUCED IN THE LIVER AS AN ACUTE YELLOW ATROPHY. CARBON TETRACHLORIDE EXPOSURE POTENTIATES THE TOXICITY OF PCB. IT WOULD APPEAR THAT IN RATS, THE ACUTE TOXICITY OF PCB'S (LD_{50} VALUES) DECREASES WITH INCREASE IN CHLORINE CONTENT. HOWEVER, IN THE RABBIT, ON SKIN TESTING, THERE IS A TREND TOWARD INCREASED TOXICITY WITH AN INCREASE IN CHLORINE CONTENT UP TO 54% WHERE THERE IS A DECREASE IN TOXICITY. WITH RESPECT TO HEPATOTOXIC ACTION OF CHLORINATED DIPHENYLS, RISEBROUGH AND BRODINE AND SAX CLAIM THAT THE HIGHER THE CHLORINE CONTENT OF THE DIPHENYL COMPOUND, THE MORE TOXIC IT IS LIKELY TO BE. OXIDES OF CHLORINATED DIPHENYLS ARE MORE TOXIC THAN THE UNOXIDIZED MATERIALS. LIKE THE SKIN LESION PRODUCED BY 2,4,5-T AND 2,4-D AND THE DIOXINS, THE CLINICAL OBSERVATIONS IN OCCUPATIONAL EXPOSURE ARE THAT OF CHLORACNE. FROM SYSTEMIC INTOXICATION THE USUAL SYMPTOMS ARE NAUSEA, VOMITING, WEIGHT LOSS, JAUNDICE, EDEMA AND ABDOMINAL PAIN. IF THERE IS EXTENSIVE LIVER PATHOLOGY, THE HIGHLY EXPOSED INDIVIDUAL MAY BECOME COMATOSE AND DIE.

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DATA FROM LONG-TERM ANIMAL STUDIES ARE AVAILABLE TO SHOW THAT THE NO-EFFECT LEVEL IN RATS AND DOGS (FOR PCB'S WITH 42, 54, AND 60% CHLORINATION) IS 10 PARTS PER MILLION (PPM). EMPLOYING A 100 TO 1 SAFETY FACTOR, THE "NO-EFFECT LEVEL FOR MAN WOULD BE 2.5 MICROGRAM (MCG/KILOGRAM (KG) BODY WEIGHT/DAY BASED ON DATA DERIVED FROM DOGS, OR 3 MCG/KG BODY WEIGHT/DAY FROM RATS. THEREFORE, BASED ON LONG-TERM ANIMAL STUDIES, THE ALLOWABLE LEVEL OF PCB INGESTION IN MAN WOULD BE APPROXIMATELY 75 MCG/DAY FOR A 70 KG INDIVIDUAL.

HUMAN INTOXICATION WITH KANACHLOR 400, A PCB MANUFACTURED IN JAPAN WITH 48% CHLORINE WAS NOTED WHEN A HEAT EXCHANGER LEAKED FLUID INTO RICE OIL AND WAS CONSUMED BY JAPANESE FAMILIES IN 1968. ABOUT 1,000 PEOPLE WERE EVENTUALLY AFFECTED. TYPICAL CLINICAL FINDINGS INCLUDED CHLORACNE AND INCREASED PIGMENTATION, VISUAL IMPAIRMENT DUE TO HYPERSECRETION OF THE MEIBOMIAN GLANDS, AND SYSTEMIC GASTROINTESTINAL SYMPTOMS THAT INCLUDED ABDOMINAL PAIN AND DISTURBANCES IN LIVER FUNCTION. A FEW BABIES WERE BORN WITH DECREASED BIRTH WEIGHTS AND SKIN DISCOLORATION WHICH SLOWLY REGRESSED AS THE CHILDREN GREW IN SIZE, ALTHOUGH THE GROWTH RATE OF MALES APPEARED TO BE SOMEWHAT SLOWER THAN NORMAL. ADULT PATIENTS HAD PROTRACTED CLINICAL DISEASE WITH VERY SLOW REGRESSION OF SYMPTOMS AND SIGNS SUGGESTING SLOW METABOLISM AND EXCRETION OF THIS PCB IN HUMANS, PROBABLY INVOLVING A LONG BIOLOGICAL HALF-LIFE. EXPOSURE LEVELS TO THE OIL WERE CALCULATED TO APPROXIMATELY, ON THE AVERAGE, 15,000 MG PER DAY. THE OIL ITSELF WAS REPORTEDLY CONTAMINATED AT A LEVEL OF ABOUT 2,000 PPM. THIS LEVEL WAS DERIVED FROM THE KNOWN ORGANIC CHLORINE CONTENT OF RICE OIL RELATED TO THE KNOWN ORGANIC CHLORINE CONTENT OF KANACHLOR 400. THE AVERAGE TOTAL

DOSE OF PCB'S CAUSING AN EFFECT IN THE JAPANESE WAS REPORTED TO BE 2,000 MG. THE HUMAN DATA PUBLISHED BY KARATSUNE, ET AL., FUKUOKA ACTA. MED. 23:117 (1971) ESTABLISHED THAT THE LOWEST LEVEL OF PCB THAT PRODUCED AN EFFECT IN MAN (USING A 50 KG MAN) WAS 500 MG CONSUMED OVER A PERIOD OF 50 DAYS AT A RATE OF APPROXIMATELY 200 MCG/KG BODY WEIGHT/DAY. THE EFFECT LEVEL WAS BASED ON OVERT SYMPTOMS RATHER THAN SENSITIVE BIOCHEMICAL TESTS THAT MIGHT HAVE DEMONSTRATED SOME EFFECTS AT EVEN LOWER LEVELS. EMPLOYING A SAFETY FACTOR OF 10 TO 1 TO GO FROM AN EFFECT LEVEL IN MAN TO A PERMISSIBLE NO-EFFECT LEVEL IN MAN ALLOWS FOR AN INGESTION OF 20 MCG/KG BODY WEIGHT/DAY; OR 1.4 MG/DAY FOR A 70 KG MAN BASED ON A TOTAL PERIOD OF EXPOSURE OF 50 DAYS (EQUIVALENT TO THE JAPANESE INCIDENT). SINCE PCB'S PROBABLY HAVE A LONG BIOLOGICAL HALF-LIFE IN MAN, AN ALTERNATIVE TOXICOLOGICAL ANALYSIS OF THE HUMAN DATA MAY BE BASED ON THE ASSUMPTION THAT INGESTED PCB'S WOULD CONTINUE TO ACCUMULATE IN TISSUES FOR A LONG PERIOD OF TIME. SINCE 2,000 MG WAS REPORTED TO BE THE AVERAGE TOTAL DOSE CAUSING AN EFFECT IN THE JAPANESE, IT IS POSSIBLE THAT 200 MG TOTAL DOSAGE PCB'S (APPLYING A SAFETY FACTOR OF 10 TO 1 AS ABOVE) MAY BE TOLERATED OVER A MUCH MORE PROTRACTED PERIOD OF TIME WITHOUT OVERT ADVERSE EFFECT IF DAILY EXPOSURE IS HELD TO MINIMAL LEVELS. IT WOULD TAKE 22 MONTHS OF DAILY INGESTION OF 300 MCG OF PCB'S TO ARRIVE AT A TOTAL INGESTION OF 200 MG. THIS WOULD PERMIT INGESTION OF 4 MCG/KG/DAY AS DERIVED FROM A 70 KG MAN. SINCE THE LOWEST TOTAL DOSE PRODUCING AN EFFECT IN MAN WAS 500 MG, A SIMILAR ANALYSIS LEADS TO AN ALLOWABLE PROTRACTED INGESTION OF 1 MCG/KG/DAY AS DERIVED FROM A 70 KG MAN.

USING THE HUMAN TOXICOLOGICAL DATA DESCRIBED ABOVE, FDA CONCLUDES THAT FOR THE SHORT TERM, BASED ON THE LOWEST TOTAL DOSE PRODUCING AN EFFECT AND ESTIMATED BIOLOGICAL HALF-LIFE OF PCB'S, CURRENT LEVELS OF PCB'S IN THE DIET REPRESENT NO IMMEDIATE HAZARD. THIS IS ALSO TRUE FOR THE AVERAGE TOTAL DOSE CAUSING AN EFFECT IN THE JAPANESE FOR LONG-TERM EXPOSURE. HOWEVER, BASED ON THE MOST SENSITIVE "JAPANESE PATIENT" (I.E., LOWEST TOTAL DOSE PRODUCING AN EFFECT), THE POSSIBILITY OF POTENTIAL LONG-TERM HAZARDS NECESSITATES REDUCTION OF THE LEVELS OF PCB'S IN FOOD AS SOON AS POSSIBLE. IN THE INTERIM, TEMPORARY TOLERANCES ARE NECESSARY TO LIMIT HUMAN EXPOSURE TO THOSE FOODS THAT MAY CONTAIN PCB'S RESULTING FROM ENVIRONMENTAL CONTAMINATION, WHICH AS A PRACTICAL MATTER ARE PRESENTLY UNAVOIDABLE. THOSE FOODS, FOR WHICH TEMPORARY TOLERANCES ARE BEING ESTABLISHED, INCLUDE MILK AND DAIRY PRODUCTS, POULTRY, EGGS, FISH, AND INFANT AND JUNIOR FOOD. INFANTS AND YOUNG CHILDREN CONSUME A GREATER AMOUNT OF FOOD PER KILOGRAM OF BODY WEIGHT AND THEREBY HAVE A PROPORTIONATELY GREATER EXPOSURE THAN DO ADULTS. A SEPARATE TEMPORARY TOLERANCE FOR INFANT AND JUNIOR FOOD, THEREFORE, REFLECTS THE POSSIBILITY THAT UNDESIRABLE EXPOSURES COULD RESULT IF COMBINATIONS OF CERTAIN PCB-CONTAMINATED FOODS COMPRISE A MAJOR PORTION OF THIS AGE GROUP'S DIET. IN ORDER TO MINIMIZE THE OVERALL DIETARY INTAKE OF PCB'S, INDIVIDUAL SOURCES OF PCB CONTAMINATION MUST ALSO BE APPROPRIATELY MINIMIZED. PCB'S HAVE BEEN SHOWN TO OCCUR IN PACKAGED FOOD AS A RESULT OF THE PCB CONTAMINATION OF PAPER FOOD-PACKAGING MATERIALS. LIMITATIONS ON THE LEVELS OF PCB'S IN PAPER FOOD-PACKAGING MATERIALS ARE, THEREFORE, NECESSARY TO

MINIMIZE THE AMOUNT OF PCB'S WHICH MAY MIGRATE TO THE PACKAGED FOOD. SINCE PCB'S CAN BE TRANSMITTED TO AND CONCENTRATED IN EDIBLE PORTIONS OF FOOD-PRODUCING ANIMALS INGESTING PCB-CONTAMINATED FEED, ANIMAL FEED REPRESENTS ANOTHER SOURCE OF PCB'S IN THE FOOD SUPPLY. LIMITATIONS ON THE LEVELS OF PCB'S IN ANIMAL FEEDS AND ANIMAL FEED COMPONENTS ARE NECESSARY, THEREFORE, TO MINIMIZE THE FREQUENCY AND MAGNITUDE OF PCB RESIDUES IN FOODS OF ANIMAL ORIGIN.

THE COMMISSIONER CONCLUDED THAT THE TEMPORARY TOLERANCES BEING ESTABLISHED WOULD PROTECT THE PUBLIC HEALTH FROM PCB'S IN FOOD, BUT CAUTIONED THAT THE TEMPORARY TOLERANCES ARE NOT TO BE CONSTRUED AS "GUIDELINES" PERMITTING THE CONSUMPTION OF FOODS CONTAINING THESE AMOUNTS OF PCB'S ON A REGULAR AND CONSISTENT BASIS. FURTHER, THE TEMPORARY TOLERANCES WILL BE LOWERED AS EXPERIENCE INDICATES THAT LOWER LEVELS CAN BE ATTAINED.

ONE COMMENT RECEIVED ON THAT PROPOSAL RECOMMENDED THAT FDA ISSUE WARNINGS TO PREGNANT WOMEN WHO BREAST FEED THEIR BABIES TO RESTRICT THEIR INTAKE OF FISH TO SPECIES THAT HAVE BEEN THOROUGHLY MONITORED BY FDA AND FOUND TO BE UNIFORMLY WITHIN THE TEMPORARY TOLERANCE. THE BASIS FOR THIS RECOMMENDATION IS THAT CONSUMPTION OF PCB-CONTAINING FISH AND, FOR THAT MATTER OTHER FOODS, MAY RESULT IN TRANSFER AND STORAGE OF PCB RESIDUES IN HUMAN MILK WHICH IN TURN, THE COMMENT CONTENDED, WOULD PRESENT A HAZARD TO BREAST FED BABIES. THE COMMISSIONER CONCLUDED THAT SUCH A WARNING IS NOT WARRANTED. ON THE BASIS OF AVAILABLE, BUT LIMITED MONITORING DATA, MOST OF WHICH IS UNPUBLISHED, IT APPEARS THAT PCB LEVELS IN HUMAN MILK WOULD GENERALLY BE LESS THAN APPROXIMATELY 0.05 PPM (WHOLE PRODUCT BASIS).

ANALYSIS OF AVAILABLE TOXICOLOGICAL DATA INVOLVING MULTIGENERATION REPRODUCTION STUDIES IN RAT INDICATES THAT THIS LEVEL PRESENTS NO IMMEDIATE HAZARD TO INFANTS. FURTHERMORE, THIS LEVEL IS SUBSTANTIALLY LESS THAN THE LEVEL OF PCB'S FDA WILL PERMIT IN THE MILK OF DAIRY COWS. THE TEMPORARY TOLERANCE BEING ESTABLISHED FOR MILK IS 2.5 PPM (FAT BASIS), WHICH IS EQUIVALENT TO 0.1 PPM (WHOLE PRODUCT BASIS).

SECTION 406 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT IS THE AUTHORITY FOR ESTABLISHING THE TEMPORARY TOLERANCES FOR PCB'S IN ANIMAL FEEDS, CERTAIN FOODS, AND PAPER FOOD-PACKAGING MATERIALS. IT STATES THAT WHERE THE ADDITION OF A POISONOUS OR DELETERIOUS SUBSTANCE TO FOOD CANNOT BE AVOIDED, THE SECRETARY SHALL PROMULGATE REGULATIONS "LIMITING THE QUANTITY THEREIN OR THEREON TO SUCH EXTENT AS HE FINDS NECESSARY FOR THE PROTECTION OF PUBLIC HEALTH," AND ALSO SPECIFICALLY STATES THAT THE SECRETARY SHALL TAKE INTO ACCOUNT THE EXTENT TO WHICH USE OF THE SUBSTANCE "CANNOT BE AVOIDED." THIS SAME AUTHORITY IS ALSO APPLICABLE TO FOOD-PACKAGING MATERIALS. THE FACT THAT THE TOLERANCES FOR PCB'S ARE TERMED "TEMPORARY" IS RECOGNITION THAT IN THE FUTURE THERE SHOULD BE LESS PCB CONTAMINATION WHICH "CANNOT BE AVOIDED," AND THE COMMISSIONER IS AUTHORIZED TO REDUCE THE TOLERANCE LEVELS ACCORDINGLY.

THE TEMPORARY TOLERANCES FOR PCB'S ARE BASED ON BOTH AN ANALYSIS OF AVAILABLE DATA ON THE TOXICOLOGICAL EFFECTS OF PCB'S AND AN ANALYSIS OF REPORTED LEVELS OF PCB'S IN THE FOOD SUPPLY.

THE RESULTS OF FDA TOTAL DIET STUDIES FOR FISCAL YEARS 1970-1972, SHOW THAT QUANTITATIVELY MEASURABLE RESIDUES OF PCB'S ARE EQUIVALENT TO AN INTAKE OF APPROXIMATELY 0.06 MCG/KG/BODY WEIGHT/DAY (OR 4.2 MCG/DAY FOR A 70 KG MAN). BECAUSE OF THE SENSITIVITY OF THE ANALYTICAL METHODS USED, PCB'S MAY BE PRESENT AT LEVELS TOO LOW TO BE DETECTED. IF LOWER LEVELS COULD BE MEASURED, THE DIETARY INTAKE OF PCB'S FROM THE TOTAL DIET STUDIES WOULD PROBABLY SHOW AN INCREASE. IT SHOULD BE RECOGNIZED, HOWEVER, THAT IN RARE INSTANCES SOME PEOPLE COULD HAVE MORE SYSTEMATIC EXPOSURES TO PCB'S IN FOODS THAN THOSE EXPECTED BY EATING A MODERATELY WELL BALANCED DIET SUCH AS REPRESENTED BY THE TOTAL DIET SAMPLES. HENCE, THERE IS A NEED FOR MINIMIZING POTENTIAL HUMAN EXPOSURES. THE TOTAL DIET STUDIES INDICATE THAT PCB'S MOST FREQUENTLY OCCUR IN THE FOOD COMPOSITE CONSISTING OF MEAT, FISH AND POULTRY (EXPERIENCE HAS SHOWN THAT MOST OF THE PCB RESIDUES IN THIS COMPOSITE ARE IN FISH AND, TO A LESSER EXTENT, POULTRY) AND IN THE FOOD COMPOSITE CONSISTING OF GRAIN AND CEREAL PRODUCTS (EXPERIENCE HAS SHOWN MOST OF THE PCB RESIDUES IN THIS COMPOSITE ARE DERIVED FROM PAPER PACKAGING MATERIALS). FDA'S FOOD SURVEILLANCE ACTIVITIES HAVE SHOWN THAT PCB'S ALSO OCCUR IN DAIRY PRODUCTS, EGGS, AND PACKAGED FOODS, IN ADDITION TO PACKAGED CEREAL PRODUCTS.

What is latest trend?

IN JULY 1969, FDA FURNISHED ITS FIELD LABORATORIES WITH A GLC METHOD EMPLOYING AN ELECTRON CAPTURE DETECTOR FOR DETERMINING PCB RESIDUES IN FOOD IN THE PRESENCE OF DDT, WHICH IS A MAJOR INTERFERING CHEMICAL. IMMEDIATELY, OUR FDA LABORATORIES BEGAN ANALYZING FOOD SAMPLES FOR PCB'S AND IN NOVEMBER 1969, THE FDA FIELD LABORATORIES WERE INSTRUCTED TO ANALYZE ALL RAW AGRICULTURAL COMMODITIES SAMPLED IN THE PESTICIDE PROGRAM FOR PCB'S.

NO PCB'S HAVE BEEN FOUND IN FRESH FRUITS AND VEGETABLES. THIS FINDING IS INDEED SIGNIFICANT BECAUSE THOUSANDS OF SAMPLES HAVE BEEN ANALYZED. PCB'S HAVE, HOWEVER, BEEN FOUND IN A FEED BY-PRODUCT FROM POTATO PROCESSING *Which process*
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PLANTS. THE SOURCE OF THE CONTAMINATION COULD NOT BE IDENTIFIED. OF ALL FOODS, PCB'S ARE ENCOUNTERED MOST FREQUENTLY IN FISH; THE FISH FROM LAKE MICHIGAN, PARTICULARLY THE COHO SALMON, USUALLY CONTAIN HIGHER LEVELS THAN OTHER DOMESTIC LAKE OR RIVER FISH. THE INCIDENCE OF DETECTABLE PCB RESIDUES IS LOWER IN SALT WATER FISH (25% AS OPPOSED TO 66% IN FRESH WATER FISH, BASED ON RATHER LIMITED FDA DATA) AND THE PCB LEVELS IN SALT WATER FISH ARE ALSO LOWER. CONFRONTED WITH THE PROBLEM OF A HIGH PERCENTAGE OF FRESH WATER FISH CONTAINING EXCESSIVE LEVELS OF PCB'S, FDA, IN FEBRUARY 1970, SET AN ACTION LEVEL OF FIVE PARTS PER MILLION IN THE EDIBLE PORTION OF THE FISH. INCIDENTALLY, YOU WILL NOTE THAT THE ACTION LEVEL FOR PCB'S IN FISH IS THE SAME AS OUR ADMINISTRATIVE GUIDELINE FOR DDT IN FISH.

IN JULY 1971, SOMEWHAT UNEXPECTEDLY, ONE OF FDA'S ROUTINE ANALYSES OF A TOTAL DIET SAMPLE FOR PESTICIDE RESIDUES SHOWED A SMALL AMOUNT OF PCB'S IN THE FOOD COMPOSITE CONSISTING OF GRAIN AND CEREAL PRODUCTS. FURTHER INVESTIGATION SHOWED THAT PCB'S WERE PRESENT IN ONLY ONE COMPONENT OF THE COMPOSITE; NAMELY, SHREDDED WHEAT BISCUIT. THE PAPERBOARD DIVIDERS USED TO SEPARATE THE INDIVIDUAL BISCUITS WERE FOUND TO CONTAIN A HIGH LEVEL OF PCB'S AND PRESUMABLE CONTAMINATED THE BISCUITS. A FOLLOW UP AT THE PAPER MILL INDICATED THAT THE DIVIDERS HAD BEEN PRODUCED FROM RECYCLED PAPER INCLUDING CARBONLESS COPY PAPER.

THESE FINDINGS, WHICH DEMONSTRATE THE VALUE OF FDA'S CONTINUING TOTAL DIET STUDIES, SUGGESTED FOOD PACKAGING MADE FROM RECYCLED PAPER AS A POTENTIAL

SOURCE OF PCB ENTRY INTO FOOD. THEREFORE, IN THE FALL OF 1971, FDA INSTITUTED A SPECIAL NATION-WIDE SURVEY OF FOODS PACKAGED IN PAPER MATERIALS TO DETERMINE THE EXTENT AND THE DEGREE OF THIS TYPE OF CONTAMINATION.

BOTH THE FOOD AND ITS PAPER PACKAGING WERE ANALYZED. THE INITIAL DETERMINATION WAS MADE BY GLC USING AN ELECTRON CAPTURE DETECTOR; THE SIZE OF THE RESPONSE FOR THE SAMPLE WAS COMPARED WITH THAT FOR A COMMERCIAL PCB WITH THE MOST SIMILAR GLC PATTERN (USUALLY AROCLOR 1242). POSITIVE FINDINGS WERE CONFIRMED, WHEN DEEMED NECESSARY, BY HALOGEN-SPECIFIC GLC DETECTION OR BY RECHROMATOGRAPHING AFTER ALKALI TREATMENT.

ALL PAPER PACKAGING MATERIAL WAS CLASSIFIED, AS DEFINITELY AS POSSIBLE, AS BEING MADE FROM RECYCLED OR VIRGIN MATERIAL. IF ANY COMPONENT OF THE PACKAGING WAS RECYCLED, ALL OF THE PACKAGING COMPONENTS OF THAT SAMPLE WERE PLACED UNDER THE HEADING OF RECYCLED PACKAGING MATERIAL. AS MIGHT BE EXPECTED, PCB LEVELS IN VIRGIN PACKAGING MATERIAL ARE SIGNIFICANTLY LOWER THAN THOSE IN RECYCLED PACKAGING MATERIAL, AND OF COURSE, THE PACKAGED FOOD ALSO SHOWS THIS DIFFERENCE. THE OVERALL AVERAGE OF PCB'S IN ALL PACKAGED FOOD WAS 0.1 PPM.

IN REGARD TO THOSE CASES WHERE PCB RESIDUES WERE FOUND IN PACKAGING COMPONENTS THAT APPEARED TO BE COMPOSED OF VIRGIN MATERIAL, IT IS POSSIBLE THAT SOME OF THE PACKAGING MAY HAVE BEEN INCORRECTLY CLASSIFIED. IN ADDITION, IT IS ALSO LIKELY THAT VIRGIN PACKAGING MAY HAVE PICKED UP PCB'S FROM THE WATER IN THE PAPER PULPING OPERATION, FROM CHEMICALS OR EQUIPMENT IN THE PAPER MILL, OR FROM THE PACKAGE MANUFACTURING OPERATION.

IN SOME INSTANCES, PCB'S WERE PRESENT IN THE PACKAGING, BUT NONE WERE FOUND IN THE FOOD. THIS CONDITION COULD BE DUE TO SUCH FACTORS AS INSUFFICIENT TIME FOR MIGRATION TO OCCUR OR A RELATIVELY IMPERVIOUS PACKAGING COMPONENT BETWEEN THE FOOD AND THE PAPERBOARD. ON THE OTHER HAND, A FEW FOOD SAMPLES CONTAINED PCB RESIDUES EVEN THOUGH NONE WAS FOUND IN THE PACKAGING.

THE INCIDENCE OF PCB RESIDUES REPORTED IN FOOD SAMPLES WHICH WERE PACKAGED IN RECYCLED PACKAGING COMPONENTS WAS 15.8% OF THE TOTAL SAMPLES, WHILE IN FOOD PACKAGED IN VIRGIN MATERIALS, THIS INCIDENCE WAS 3.4% OF THE TOTAL SAMPLES. THUS, A TOTAL OF ABOUT 19% OF ALL FOODS SAMPLED CONTAINED PCB RESIDUES. THE INCIDENCE OF PCB'S WAS HIGHEST IN THE INFANT CEREALS CATEGORY (75%), BUT ONLY 16 SAMPLES IN THIS CATEGORY WERE EXAMINED. HOWEVER, IT MAY BE SIGNIFICANT THAT 14 OF THE 16 SAMPLES WERE PACKAGED IN RECYCLED PAPER. THE INCIDENCE OF PCB RESIDUES WAS IN THE RANGE OF 20-40% IN THE CATEGORIES OF RICE, OATMEAL, AND FARINA; DRIED FRUIT; AND PREPARED MIXES.

A REVIEW OF THE INDIVIDUAL SAMPLE REPORTS SHOWED THAT WHEN THE FOOD CONTAINED 0.5 PPM OR MORE PCB'S, IN ALL BUT ONE CASE, IT HAD BEEN IN DIRECT CONTACT WITH PACKAGING MATERIAL CONTAINING PCB'S. THIS SURVEY INDICATES THAT A PRINCIPAL SOURCE OF PCB RESIDUES IN FOODS PACKAGED IN PAPER PRODUCTS IS PCB'S IN THE PACKAGING MATERIAL.

BASED IN PART ON THESE FINDINGS, THE REGULATIONS PROPOSING TEMPORARY TOLERANCES FOR PCB'S, PUBLISHED IN MARCH 1972, INCLUDED FOOD PACKAGING MATERIAL. THE FINAL REGULATIONS, PUBLISHED JULY 6, 1973, CONTINUED TO INCLUDE FOOD PACKAGING MATERIALS ALTHOUGH THERE WERE EXTENSIVE COMMENTS SUBMITTED REQUESTING CHANGES OR MODIFICATIONS.

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BECAUSE IT WAS ISSUED UNDER SECTION 406 OF THE ACT, AND THUS WAS SUBJECT TO OBJECTIONS AND REQUESTS FOR A PUBLIC HEARING PURSUANT TO SECTION 701(E) OF THE ACT (AS CONTRASTED WITH THE PROVISIONS OF SECTION 701(A) WHICH DO NOT REQUIRE A PUBLIC HEARING), WE INCLUDED IN THE REGULATION A STATEMENT THAT WE WOULD ENFORCE THE TOLERANCE LIMITATIONS IMPOSED UNDER THIS REGULATION BY SEIZURES UNDER THE ADULTERATION PROVISIONS OF THE LAW IF OBJECTIONS AND REQUESTS FOR A PUBLIC HEARING WERE RECEIVED. AS WE ANTICIPATED, OBJECTIONS AND REQUESTS FOR A PUBLIC HEARING WERE IN FACT FILED. NO PUBLIC HEARING HAS YET BEEN ANNOUNCED.

"SUIT WAS BROUGHT AGAINST US BY A PAPERBOARD COMPANY CONTENDING THAT FOOD PACKAGING IS NOT SUBJECT TO REGULATION BY FDA UNDER THE FD&C ACT, BECAUSE IT IS NOT "FOOD" WITHIN THE MEANING OF THE ACT, AND THUS THAT THE THREATENED SEIZURES SHOULD BE ENJOINED. THE DISTRICT COURT RULED THAT IT DID NOT HAVE JURISDICTION TO ENJOIN SEIZURES OR TO ISSUE A DECLARATORY JUDGMENT ON THE LEGAL ISSUE PRESENTED."

"WE HAD URGED THE DISTRICT COURT THAT IT DID HAVE JURISDICTION TO ISSUE A DECLARATORY JUDGMENT ACTION DECIDING THE LEGAL ISSUE INVOLVED, BUT THAT IT COULD NOT ENJOIN SEIZURES PENDING THE OUTCOME OF THAT DECLARATORY JUDGMENT. WE ALSO URGED THE DISTRICT COURT TO DECIDE THAT FOOD PACKAGING WHICH RESULTS IN MIGRATION IN SUBSTANCES TO FOOD IS "FOOD" WITHIN THE MEANING OF THE ACT."

"ON APPEAL, WE AGAIN URGED THE POSITION THAT WE TOOK IN THE LOWER COURT. THE DEPARTMENT OF JUSTICE AT FIRST DECLINED TO ESPOUSE OUR VIEW, BUT LATER WAS PERSUADED TO DO SO. THIS INVOLVED RECONCILING TWO DIFFERENT SUPREME COURT

DECISIONS - THE MYTINGER & CASSELBERRY AND ABBOTT LABS CASES - IN A WAY THAT HAD NOT YET BEEN DECIDED BY THE COURTS. IN MYTINGER & CASSELBERRY, THE SUPREME COURT HELD THAT CONGRESS INTENDED FDA TO BE ABLE TO MAKE SEIZURES OF PRODUCTS PENDING A COURT DETERMINATION OF THEIR LEGALITY, AND THUS THAT A DISTRICT COURT COULD NOT ENJOIN SEIZURES PENDING LITIGATION ON THE MERITS OF AN ISSUE. IN ABBOTT LABS., THE SUPREME COURT CONCLUDED THAT INDUSTRY IS ENTITLED TO OBTAIN A DECLARATORY JUDGMENT WITH RESPECT TO ANY CONTROVERSY IT MAY HAVE WITH FDA, AND NEED NOT AWAIT SPECIFIC ENFORCEMENT ACTION (A SEIZURE) BEFORE SUCH A COURT DETERMINATION."

"WE ARGUED THAT THESE TWO SUPREME COURT DECISIONS SHOULD BE RECONCILED IN THE FOLLOWING WAY. FIRST, FDA IS ENTITLED TO SEIZE ANY PRODUCT UNDER THE ACT, AND TO CONTINUE TO MAKE SUCH SEIZURES (WHERE MULTIPLE SEIZURES ARE AUTHORIZED), UNTIL THERE IS A DEFINITIVE COURT DECISION ADJUDICATING THE LEGALITY OF THE PRODUCTS INVOLVED. SECOND, THE LEGALITY OF THOSE PRODUCTS MAY BE ASCERTAINED THROUGH LITIGATION ARISING EITHER AS A RESULT OF FDA ENFORCEMENT ACTION (A SEIZURE), OR A DECLARATORY JUDGMENT INITIATED BY INDUSTRY. UNDER OUR INTERPRETATION, THEREFORE, FDA WOULD BE FREE TO BRING SEIZURE ACTIONS EVEN AFTER A DECLARATORY JUDGMENT ACTION IS INSTITUTED BY INDUSTRY, AND THE DISTRICT COURT WOULD BE POWERLESS TO ENJOIN SUCH SEIZURES UNLESS AND UNTIL IT DECIDES THE ISSUE ON ITS MERITS."

"IN ITS DECISION OF JUNE 3, 1974, ON PCB'S, THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT AGREED FULLY WITH OUR POSITION."

FOR THOSE OF US INVOLVED IN THE REGULATION OF FISH FROM LAKE MICHIGAN, THERE IS A SECOND COURT CASE WHICH IS ALSO OF INTEREST AND HAS A BEARING ON THIS ISSUE. IN U.S. VS. VITA FOOD PRODUCTS OF ILLINOIS, INC., WE ALLEGED IN PART THAT THE DEFENDANT RECEIVES AFTER SHIPMENT IN INTERSTATE COMMERCE, ARTICLES OF FOOD CONSISTING OF FISH, KNOWN AS CHUBS, AND DISTRIBUTES THEM FOR HUMAN CONSUMPTION AND THAT THESE CHUBS ARE ADULTERATED WITHIN THE MEANING OF 21 U.S.C. 342(A)(2)(C) IN THAT THEY CONTAIN FOOD ADDITIVES; NAMELY, THE CHEMICAL SUBSTANCES, DDT, DERIVATIVES OF DDT, AND DIELDRIN, WHICH ARE UNSAFE WITHIN THE MEANING OF 21 U.S.C. 348(A). THE GOVERNMENT FURTHER ALLEGES THAT THE ABOVE-NAMED ADDITIVES AND THEIR USE AND INTENDED USE ARE NOT IN CONFORMITY WITH A REGULATION OR EXEMPTION ISSUED PURSUANT TO 21 U.S.C. 348(A), "SINCE THE TOATL AMOUNT OF DDT AND ITS DERIVATIVES PRESENT IN SAID SMOKED CHUB IS AT A LEVEL IN EXCESS OF THE INTERIM LIMIT OF 5 PPM WHICH WAS ESTABLISHED BY THE FOOD AND DRUG ADMINISTRATION FOR ALL FISH PURSUANT TO AN ANNOUNCEMENT TO THE PUBLIC ON APRIL 22, 1969, AND WHICH IS STILL IN EFFECT. THE DISTRICT COURT DID NOT ACCEPT THE GOVERNMENT'S ARGUMENTS. THAT COURT FOUND IN PART AS FOLLOWS:

I FIND THAT 21 U.S.C. 342(A)(2)(C) IS NOT APPLICABLE SINCE DDT, DERIVATIVES OF DDT AND DIELDRIN FOUND IN VITA'S SMOKED CHUBS ARE NOT "FOOD ADDITIVES" UNDER THE ACT. I FIND THAT DDT, DERIVATIVES OF DDT AND DIELDRIN AS FOUND IN VITA'S SMOKED CHUBS ARE NOT A KNOWN HEALTH HAZARD WITHIN THE MEANING OF 21 U.S.C. 342(A)(1). I FIND THAT THE TEST METHOD TO BE USED BY PROCESSORS OF SMOKED CHUB IS NOT SUFFICIENTLY PRECISE FOR A FINDING OF FACT THAT THE CHUBS SAMPLED IN APRIL 1972, CONTAINED DDT CONCENTRATIONS IN EXCESS OF 5 PPM.

THIS FINDING WAS REVERSED ON APPEAL. ON AUGUST 28, 1974, THE CIRCUIT COURT OF APPEALS FOUND IN TWO PARTS OF THEIR DECISION AS FOLLOWS:

THUS, THE TOLERANCES FOR DDT AND DIELDRIN IN OR ON RAW FRUITS, VEGETABLES, AND MEAT ARE ADEQUATE TO AVOID ADULTERATION CAUSED BY THE RESIDUES REMAINING AFTER THE FOODS ARE PROCESSED. WITHOUT SUCH TOLERANCES, WE THINK IT IS CLEAR THAT THE PRESENCE OF DDT IN OR ON SUCH FOODS WILL CAUSE ADULTERATION PURSUANT TO SUBPARAGRAPH (A)(2)(B) IN THEIR RAW STATE, AND THAT THE SAME CONSEQUENCE WILL FOLLOW FROM SUBPARAGRAPH (A)(2)(C) AFTER PROCESSING. WE ARE ALSO PERSUADED THAT THESE CHEMICALS HAVE THE SAME IMPACT ON FISH IN THE GREAT LAKES. AS LONG AS NO TOLERANCES HAVE BEEN ESTABLISHED, THE RAW CHUBS ARE ADULTERATED WITHIN THE MEANING OF (A)(2)(B) BECAUSE THEY CONTAIN AN UNSAFE PESTICIDE CHEMICAL; AFTER PROCESSING, BY VIRTUE OF (A)(2)(C), THE CHUBS ARE ADULTERATED BECAUSE THEY CONTAIN AN UNSAFE FOOD ADDITIVE. WE THINK THIS IS EVIDENT FROM THE ENTIRE STATUTORY SCHEME, THE DEFINITIONAL LANGUAGE, AND THE RELEVANT LEGISLATIVE HISTORY. WE HOLD, THEREFORE, THAT THE DDT AND DIELDRIN FOUND IN DEFENDANTS' SMOKED CHUBS WERE "FOOD ADDITIVES" AND, SINCE NOT PROTECTED BY ANY TOLERANCE, THE CHUBS WERE "ADULTERATED" AS A MATTER OF LAW.

AND

THE DISTRICT COURT CONSIDERED THE AOAC METHOD OF TESTING FOR CHEMICAL RESIDUES INSUFFICIENTLY PRECISE FOR THE GOVERNMENT TO SUSTAIN ITS BURDEN. IT IS CLEAR, HOWEVER, THAT THE ENFORCEMENT GUIDELINES MUST HAVE BEEN ADOPTED ON THE ASSUMPTION - SHARED BY GOVERNMENT AND INDUSTRY - THAT EXISTING METHODS OF TESTING DDT WERE SUFFICIENTLY ACCURATE TO PERMIT MEANINGFUL ADMINISTRATION OF

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THE LIMITS SPECIFIED THEREIN. THE AOAC METHOD WAS USED BY BOTH THE GOVERNMENT TECHNICIANS AND BY THE EXPERT EMPLOYED BY APPELLANT. HOWEVER IMPRECISE THAT METHOD MAY BE, THE RECORD INDICATES THAT IT IS THE BEST METHOD THAT CAN BE USED. CERTAINLY, THE GOVERNMENT MUST BE PERMITTED TO USE THE BEST TESTING METHOD YET DEvised BY ANALYTICAL CHEMISTS, FOR THE ENFORCEMENT GUIDELINES MUST HAVE BEEN PREDICATED UPON THAT METHOD. THEREFORE, WITHOUT DISAGREEING WITH THE DISTRICT COURT'S OBSERVATION THAT THE AOAC METHOD FALLS SHORT OF PERFECT CERTAINTY, WE CANNOT ACCEPT THE VIEW THAT IT MAY NOT BE USED TO EVALUATE APPELLANTS' COMPLIANCE WITH THE GUIDELINES. THE DISTRICT COURT'S CONTRARY DETERMINATION WAS CLEARLY ERRONEOUS.

THESE COURT DECISIONS ARE VERY HELPFUL IN CLARIFYING OUR AUTHORITY TO ACT AND IN REAFFIRMING THE VALIDITY OF THE 5 PPM TEMPORARY GUIDELINE FOR PCB'S IN FISH. THIS THEN BRINGS US TO THE PROBLEMS OF LAKE MICHIGAN AND THE CONTAMINATION OF THE FISH IN THAT LAKE.

CAREFUL ANALYSIS BY MANY INVESTIGATORS CONFIRMS THE PRESENCE OF SEWAGE DISCHARGES INTO LAKE MICHIGAN WHICH CONTAIN PCB'S AND ALSO CONFIRM A CONSIDERABLE BIOLOGICAL MAGNIFICATION IN FISH. CONTINUING EFFORTS BY THE VARIOUS STATES AND THE FEDERAL GOVERNMENT ARE NECESSARY TO ELIMINATE SUCH DISCHARGES. UNFORTUNATELY, DESPITE THE MANUFACTURER'S REDUCTION OF DELIBERATE USES OF THESE CHEMICALS, WE RECENTLY LEARNED OF A SERIES OF INCIDENTS IN WHICH SILOS WERE NEWLY PAINTED WITH PCB CONTAINING PAINT WITH THE RESULTANT CONTAMINATION OF A NUMBER OF DAIRY HERDS.

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THE PERSISTENT NATURE OF PCB'S IN THE ENVIRONMENT AND THEIR LONG HALF-LIVES IN ZOOLOGICAL SYSTEMS MEANS THAT A REAL PROBLEM FACES US IN DEALING WITH BOTH COMMERCIAL AND SPORTS FISHING IN LAKE MICHIGAN. THE MOST COMPLETE SURVEY OF PCB LEVELS IN LAKE MICHIGAN FISH WHICH I HAVE SEEN IS ONE REPORTED BY THE GREAT LAKES ENVIRONMENTAL CONTAMINANTS SURVEY. THE MICHIGAN DEPARTMENT OF AGRICULTURE, MICHIGAN DEPARTMENT OF NATURAL RESOURCES, THE DETROIT DISTRICT OFFICE OF FDA, AND THE USDI BUREAU OF SPORT FISHERIES - ANN ARBOR LAB JOINED TOGETHER IN THIS SURVEY. THEIR SUMMARY REPORTS ARE PREPARED BY THE MICHIGAN DEPARTMENT OF AGRICULTURE. SUMMARIES FOR 1972 AND 1973, HAVE BEEN PREPARED. THE SUMMARY FROM 1974, HAS NOT YET BEEN COMPLETED. THESE REPORTS REFER TO THE SEVERAL GREAT LAKES AND LAKE ST. CLAIRE. FOR PURPOSES OF THIS MEETING, I HAVE EXTRACTED THE RESULTS FOR LAKE MICHIGAN FROM THE COPIES MADE AVAILABLE TO ME. I DO WANT TO MAKE CERTAIN, HOWEVER, THAT FULL CREDIT AND SPECIAL THANKS GOES TO THOSE WHOSE WORK IS REPRESENTED, ESPECIALLY THE MICHIGAN DEPARTMENT OF AGRICULTURE.

THIS SERIES OF TABLES WAS PREPARED BY EXTRACTING FROM THE 1972 AND 1973, REPORTS REFERRED TO ABOVE. THE ORIGINAL REPORTS CARRY INFORMATION ON ADDITIONAL ADULTERANTS AS WELL AS ADDITIONAL BODIES OF WATER, BUT I WANTED TO CONCENTRATE YOUR ATTENTION ON THE PCB FINDINGS. THE PROBLEMS IN RELATION TO THE 5 PPM LIMIT FOR PCB'S ARE OBVIOUS FOR STEELHEAD, CHUBS, BOTH COMO AND CHINOOK, SALMON AND LAKE TROUT. THESE ARE OBVIOUSLY PROBLEMS WHICH WILL NOT GO AWAY QUICKLY.

FLEETING STUDIES WITH MINK HAVE SHOWN A STRONG ADVERSE REACTION IN LITTER REDUCTION AND EVEN DEATH OF ADULTS. DAIRY COWS FREELY PASS PCB'S FROM

THEIR FEED TO THE MTLK. SUCH RESULTS CLEARLY SHOW THAT DIVERSION OF PCB ADULTERATED FISH TO ANIMAL FOOD IS A HAZARDOUS ALTERNATIVE. WE NEED TO JOINTLY FIND A SOLUTION TO THIS COMPLEX PROBLEM. OBVIOUSLY, WE MUST PREVENT OR DRASTICALLY REDUCE DISCHARGES OF PCB'S INTO THE LAKES. SECOND, WE NEED TO FIND WAYS TO REDUCE THE ZOOLOGICAL HALF-LIFE OF THESE CHEMICALS. THIRD, WE SHOULD TAKE A UNIFORM STAND ON THE USE OF THESE FISH FOR HUMAN FOOD.

ON DECEMBER 6, 1974, THE FDA PUBLISHED PROPOSED REGULATIONS DEFINING TOLERANCES AND ACTION LEVELS AS THEY RELATE TO ADDED POISONOUS OR DELETERIOUS SUBSTANCES. ON THAT SAME DATE, WE ALSO REPUBLISHED THE TEMPORARY TOLERANCE FOR PCB'S IN FISH AT 5 PPM. THIS SAME ISSUE ALSO CARRIED A SECTION IN WHICH THE COMMISSIONER RESERVES THE RIGHT TO EXEMPT FOODS FROM REGULATORY ACTION IF HE DETERMINES (1) BASED UPON ALL AVAILABLE SCIENTIFIC EVIDENCE, THAT THE FOOD IS SAFE FOR CONSUMPTION AND (2) THAT DESTRUCTION OR DIVERSION OF THE FOOD INVOLVED WOULD RESULT IN A SUBSTANTIAL ADVERSE IMPACT ON THE NATIONAL FOOD SUPPLY.

I DO NOT BELIEVE THAT CHUBS, LAKE TROUT, OR SALMON FROM LAKE MICHIGAN WOULD MEET THESE EXEMPTIONS. THE TOXICOLOGY DATA GIVEN ABOVE WOULD MAKE THE PRODUCT FAIL THE "SAFE FOR CONSUMPTION" CRITERIA. LAKE TROUT AND BOTH COHO AND CHINOOK SALMON ARE LIMITED TO SPORTS FISHING AND CHUBS FILL ONLY A SMALL SPECIALTY MARKET. NOW THAT THE COURTS HAVE CLEARED UP THE QUESTIONS OF OUR JURISDICTION, I BELIEVE THAT FDA IS READY TO TAKE LEGAL ACTION AGAINST ALL SHIPMENTS OF FISH IN INTERSTATE COMMERCE WHICH EXCEED THE 5 PPM TEMPORARY TOLERANCE FOR PCB. THE DATA PRESENTED SHOW THAT ALL LOTS OF CHUBS FROM LAKE MICHIGAN CAN BE EXPECTED TO EXCEED THAT LIMIT AND THUS WILL BE SUBJECT TO SEIZURE.

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