APR 13 1977

R. A. Stohr - B2SC

April 13, 1977

[redacted] - B2SC
S. K. Torrey - E2ND

FDA REDUCTIONS OF
PCB TOLERANCES

Mr. J. C. Weber
B2SK

We have asked Lon MacFarland to provide us with a more readable copy of the recent telex from the FDA as to proposed reductions in PCB tolerances in foods. Note that the proposal was to have been published in the April issue of the Federal Register.

Note the paragraph at the top of the second page in which the FDA states that as a result of its efforts and the voluntary efforts of Monsanto, the levels of PCB residues in the American diet have decreased markedly in recent years.

R. A. Stohr

/dmf
Enclosure

P.S. Note: the copy furnished by Mr. MacFarland is still very difficult to read, therefore, we have typed the body of the telex for easier reading.

THE FOLLOWING "TALK PAPER" RE PCB'S IN FOOD, DATED 3/25/77, WAS ISSUED BY FDA:

THE FOOD AND DRUG ADMINISTRATION IS PROPOSING TO LOWER THE TOLERANCES FOR POLYCHLORINATED BIPHENYLS (PCB'S) THAT OCCUR AS ENVIRONMENTAL CONTAMINANTS IN FOODS.

PCB'S ARE HIGHLY STABLE CHEMICALS THAT, DUE TO INDUSTRIAL USES, HAVE BECOME PERSISTENT ENVIRONMENTAL CONTAMINANTS THAT CANNOT BE TOTALLY PREVENTED FROM ENTERING THE FOOD SUPPLY. FDA IS RESPONSIBLE FOR ESTABLISHING TOLERANCES OF LEGAL LIMITS ON THE AMOUNTS OF SUCH UNAVOIDABLE CHEMICAL CONTAMINANTS IN FOODS. ANY FOOD THAT CONTAINS MORE THAN THE LEGAL LIMIT IS SUBJECT TO FDA REGULATORY ACTION IF SHIPPED IN INTERSTATE COMMERCE.

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UNDER THE FDA PROPOSAL, THE LEGAL LIMIT FOR PCB'S WOULD BE LOWERED FROM 2.5 PARTS PER MILLION (PPM) (THAT MEANS 2.5 PARTS OF PCB'S FOR EVERY MILLION PARTS OF THE PRODUCT IN THE FAT OF MILK AND DAIRY PRODUCTS TO 1.5 PPM FROM 5 PPM to 3 PPM IN THE FAT OF POULTRY; FROM 6.5 PPM TO 6.3 PPM IN EGG; AND FROM 5 PPM to 2 PPM IN FISH AND SHELLFISH.

RECENT STUDIES EVALUATED BY FDA INDICATE THAT PCB'S FED IN HIGH DOSES CAUSE LIVER TUMORS IN LABORATORY TEST ANIMALS. (THE DELANEY CLAUSE OF THE FOOD, DRUG, AND COSMETIC ACT, WHICH PROHIBITS THE ADDITION TO FOOD OF ANY ADDITIVE THAT CAUSES CANCER IN MAN OR TEST ANIMALS, DOES NOT APPLY BECAUSE PCB'S ARE NOT INTENTIONALLY ADDED TO FOOD, BUT ENTER FOOD BECAUSE OF THEIR PRESENCE IN THE ENVIRONMENT.)

DURING A JAPANESE INCIDENT IN 1968, HUMANS ACCIDENTLY INGESTED EXTREMELY HIGH LEVELS OF PCB'S IN CONTAMINATED RICE OIL. TOXIC EFFECTS INCLUDING ACNELIKE SKIN ERUPTIONS, DARKENING OF THE SKIN AND NAILS, EXCESSIVE DISCHARGE FROM THE EYES, AND SWELLING OF THE EYELIDS WERE OBSERVED.

FDA IS PROPOSING TO LOWER THE LEGAL LIMITS FOR PCB'S IN FOOD AS PART OF ITS CONTINUING EFFORT TO REDUCE HUMAN EXPOSURE TO PCB'S. LEGAL LIMITS FOR PCB'S WERE FIRST FORMALLY ESTABLISHED BY FDA IN 1973 WITH THE INTENTION THAT THEY WOULD BE REDUCED AS CONTAMINATION LEVELS IN FOOD DUE TO UNAVOIDABLE CIRCUMSTANCES DECREASED.

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AS A RESULT OF FDA REGULATORY EFFORTS AND THE VOLUNTARY RESTRICTIONS ON INDUSTRIAL USES OF PCB's INITIATED BY MONSANTO CO., THE ONLY DOMESTIC PRODUCER OF THESE CHEMICALS, THE LEVELS OF PCB RESIDUES IN THE AMERICAN DIET HAVE DECREASED MARKEDLY IN RECENT YEARS. ONLY TRACES OF PCB RESIDUES ARE NOW BEING FOUND IN ALL FOOD CATEGORIES EXCEPT FOR FRESHWATER FISH.

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FRESHWATER FISH SUCH AS WALLEYE, BASS, COHO SALMON, AND LAKE TROUT HAVE BEEN FOUND CONTAMINATED WITH RELATIVELY HIGH LEVELS OF PCB RESIDUES. MOST OF THESE FISH ARE CAUGHT BY SPORT FISHERMEN OR COMMERCIAL FISHERMEN WHO DO NOT DO BUSINESS IN INTERSTATE COMMERCE AND ARE THEREFORE NOT SUBJECT TO FDA REGULATION.

THE PROPOSED LOWER LEGAL LIMIT FOR PCB'S WOULD APPLY ONLY TO FISH SHIPPED IN INTERSTATE COMMERCE; FISH CAUGHT AND SHIPPED WITHIN STATES ARE SUBJECT TO STATE REGULATION.

IN FEBRUARY 1976, FDA ANNOUNCED ITS SUPPORT OF A NEW YORK STATE BAN ON MOST COMMERCIAL FISHING FROM THE HUDSON RIVER AND ADVISED SPORT FISHERMEN TO LIMIT THEIR CONSUMPTION OF FISH FROM THE HUDSON AND OF SALMON CAUGHT IN LAKE ONTARIO BECAUSE OF HIGH PCB RESIDUES FOUND IN FISH FROM THOSE SOURCES.

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SIMILAR RESTRICTIONS HAVE BEEN INITIATED BY OTHER STATE AGENCIES PARTICULARLY IN THE GREAT LAKES REGION.

FDA EMPHASIZES THAT MOST FISH IN THE AMERICAN DIET COME FROM SALT WATER SOURCES AND ARE RARELY CONTAMINATED WITH PCB RESIDUES.

THE PROPOSAL TO LOWER THE LEGAL LIMITS FOR PCB'S IN FOODS WILL BE PUBLISHED IN THE FEDERAL REGISTER APRIL 1, 1977. COMMENTS WILL BE ACCPTED FOR 60 DAYS AND MAY BE SENT TO THE HEARING CLERK, FOOD AND DRUG ADMINISTRATION, ROOM 4065, 5600 FISHERS LANE, ROCKVILLE, MD. 20857.

R. Stehn
C. Weber
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DUPLICATE AND CORRECTED COPY

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PCB'S ARE HIGHLY STABLE CHEMICALS THAT, DUE TO INDUSTRIAL USES, HAVE BECOME PERSISTENT ENVIRONMENTAL CONTAMINANTS THAT CANNOT BE TOTALLY EXCLUDED FROM ENTERING THE FOOD SUPPLY. FDA IS RESPONSIBLE FOR ESTABLISHING TOLERANCES OR LEGAL LIMITS OF THE AMOUNTS OF SUCH UNAVOIDABLE CHEMICAL CONTAMINANTS IN FOODS. ANY FOOD THAT CONTAINS MORE THAN THE LEGAL LIMIT IS SUBJECT TO FDA REGULATORY ACTION IF SHIPPED IN INTERSTATE COMMERCE.

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DURING A JAPANESE INCIDENT IN 1968, PEOPLE ACCIDENTALLY INGESTED EXTREMELY HIGH LEVELS OF PCB'S IN CONTAMINATED RICE OIL. AFFECTED INDIVIDUALS SUFFERED SKIN ERUPTIONS, DISCOLORATION OF THE SKIN AND NAILS, SWELLING OF THE FEET AND HANDS, AND SPECIFICS OF THE CHILDREN WERE BORN.

FDA IS PROPOSING TO LOWER THE LEGAL LIMITS FOR PCB'S IN FOOD AS PART OF ITS CONTINUING EFFORT TO REDUCE HUMAN EXPOSURE TO PCB'S. LOWER LIMITS FOR PCB'S ARE A FIRST PARTIAL STEP TOWARD REDUCING THE INJECTION THAT FDA SHOULD BE ABLE TO ESTABLISH ACCEPTABLE LEVELS OF PCBS DUE TO UNAVOIDABLE ENVIRONMENTAL CONTAMINATION.

AS A RESULT OF FDA REGULATORY EFFORTS AND THE VOLUNTARY RESTRICTIONS ON INDUSTRIAL USES OF PCB'S INITIATED BY MONSANTO CO., THE ONLY DOMESTIC PRODUCER OF THESE CHEMICALS, THE LEVELS OF PCB RESIDUES IN THE AMERICAN DIET HAVE DECREASED MARKEDLY IN RECENT YEARS. ONLY TRACES OF PCB RESIDUES ARE NOW BEING FOUND IN ALL FOOD CATEGORIES EXCEPT FOR FRESHWATER FISH.

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GR: 620/PCT
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