STATE OF NEW YORK
DEPARTMENT OF ENVIRONMENTAL CONSERVATION

In the Matter of

Alleged Violations of Sections 17-0501, 17-0511, and 11-0503 of the Environmental Conservation Law of the State of New York by

General Electric Company

Respondent

TESTIMONY OF

DR. ALBERT C. KOLBYE

FILE NO. 2833

Q. State your name and business address.

A. Dr. Albert C. Kolbye, United States Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland.

Q. State your position at the Food and Drug Administration and your prior work and educational experience.

A. I am Associate Director for Sciences, Bureau of Foods, Food and Drug Administration. I am a licensed physician with graduate training in epidemiology and an Assistant Surgeon General in the United States Public Health Service. In February 1970 I was appointed Deputy Director of the Bureau of Foods. A copy of my Curriculum Vitae is attached to my testimony as Exhibit "1".

Q. What are your responsibilities at FDA?

A. From February 1970 to the present, it has been my responsibility to interpret the best available evidence concerning potential risks to human health and to review or initiate decisions intended to protect the public from such risks.

Q. In the course of your work at FDA, have you ever been involved in assessing the toxicity of polychlorinated biphenyls (PCBs)?

A. In exercising this responsibility, I have participated in the decisions made by the FDA with respect to protecting the public health against the hazards associated with dietary exposure to PCBs. As an exhibit to my testimony, I am attaching the Final Order Regulations FDA promulgated on Polychlorinated Biphenyls on July 6, 1973 (38 Fed. Reg. 18096). I am advised that this document has already been marked as Government Exhibit number 3 for identification. The order and its accompanying preamble explain in detail the overall problem of PCB contamination of foods, the steps taken by FDA to control this problem, the tolerances established by FDA for PCBs in fish and other foods, and the basis for these tolerances.

Q. Why has the FDA established regulations relating to PCBs?

A. PCBs are toxic industrial chemicals. Because of their past uncontrolled industrial applications and their chemical stability, PCBs are a persistent and widespread contaminant of the environment. As a result, certain foods, including those of animal and marine origin, contain PCBs, an unavoidable environmental contaminant. Because PCBs are unavoidable poisonous or deleterious substances, temporary tolerances under Section 406 of the Federal Food, Drug, and Cosmetic Act for residues of PCBs in various foods were established by FDA in order to minimize dietary intakes of PCBs.

Q. Please explain the content of the regulations in Government's Exhibit 3 for identification and the basis thereof.

A. In establishing these regulations, the Commissioner of Food and Drugs took into account available toxicological data and the extent to which PCBs in these foods are unavoidable under current Good Manufacturing Practices. On the basis of these considerations, the Commissioner established the following temporary tolerances for PCBs:

1. 2.5 ppm in milk (fat basis)

2. 2.5 ppm in manufactured dairy products (fat basis)

3. 5 ppm in poultry (fat basis)

4. 0.5 ppm in eggs

5. 0.2 ppm in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

6. 2 ppm in animal feed components of animal origin including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements and premixes intended for food-producing animals.

7. 5 ppm in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera and inedible bones.

8. 0.2 ppm in infant and junior foods.

Additionally, the FDA is enforcing an action level of 10 ppm for PCBs in paper food-packaging material pending the completion of a public hearing to establish a formal tolerance under Section 406 of the Federal Food, Drug, and Cosmetic Act.

Q. In establishing these standards, was a lifetime exposure to PCBs assumed?

A. While Deputy Director, Bureau of Foods, I had the occasion, at the Commissioner's press conference on PCBs held on September 29, 1971, to explain the philosophy on which the FDA approach to PCBs in foods was based. That philosophy was described as follows:

> Animal and human data both point to 150-300 micrograms/day as being in the range of safety as far as a temporary dietary intake over a relatively short period of time that we as a

society will be forced to tolerate the presence of these chemicals in our food supply. (emphasis added).

In other words, in calculating acceptable levels of human exposure to PCBs, FDA was assuming a less than lifetime exposure to PCBs.

Nearly one year later, in a talk before the American Chemical Society Symposium on PCBs (August 30, 1972, New York City), I reiterated the point that in establishing the temporary tolerances for PCBs, FDA was relying on the less than lifetime exposure concept.

Thus, although the FDA concluded, using the less than lifetime exposure concept, that the temporary tolerances would protect the public health, the agency cautioned that:

> these temporary tolerances are not to be construed as guidelines permitting the consumption of foods containing these amounts of PCBs on a <u>regular and consistent basis</u>. Further, the temporary tolerances will be <u>lowered</u> as experience indicates that lower levels can be attained. (Supplement to Final Environmental Impact Statement, Rulemaking on Polychlorinated Biphenyls, July 2, 1973 at 13.) (emphasis added.)

Thus, it has been clear from the outset, that FDA recognized that exposure to PCBs on a lifetime basis significantly enhanced the possibility of toxic effects from PCBs.

Q. What toxicological data was relied upon in formulating the standards and has additional data become available?

A. The temporary tolerances established in 1973 were arrived at after review and evaluation of the best available toxicological data. FDA recognizes,

however that additional scientific studies on the toxicity of PCBs have recently been completed or will be completed soon. We are reviewing or will shortly review these studies to determine whether revision of the tolerances is necessary. Much data has been gathered since the tolerances were set, including the recent study indicating that PCBs are carcinogenic in animals.1/

Data from long-term animal studies (two years) established that the no-effect level in rats and dogs for PCBs with three levels of chlorination (42, 54, or 60%) is 10 ppm. These animal data were used as a basis for estimating a no-effect level in man.2/ When data derived from dogs were used, a no-effect level of 2.5 micrograms/kg body weight/day was calculated. When rat data were used, the no-effect level in man was three micrograms/kg body weight/day. Thus, for a 70 kg individual (approximately 155 pounds), an allowable level of PCB ingestion would be 175 to 210 micrograms per day.3/

1/ Kimbrough, R.D. et al., Induction of Liver Tumors in Sherman Strain Female Rats by Polychlorinated Biphenyl Aroclor 1260, Journal of the National Cancer Institute, in press.

2/ In calculating a no-effect level for humans when an intentional food additive such as PCBs are concerned, a safety factor of 100 to 1 is incorporated. See Lehman & Fitzhugh, 100-Fold Margin of Safety, Assn. of Food and Drug Officials of the United States, Quarterly Bulletin, Vol. XVIII, No. 1 at 33, (January 1954); Procedures for Investigating Intentional and Unintentional Food Additives, Report of WHO Scientific Group, World Health Organization Technical Report Series No. 348. (1967)

3/ 2.5 x 70 = 175 mg; 3 x 70 = 210 mg.

When establishing tolerances such as those for PCBs it is preferable, although not always possible, to rely on human rather than animal data. The World Health Organization has stated that:

> Valid human data should take precedence over predictions arrived at by extrapolation from animal studies and may make it possible to apply a lower margin of safety. 4/

In the case of PCBs, human data is available from the unfortunate "Yusho" poisoning incident in Japan in 1968 in which rice oil contaminated with PCBs was consumed.

The rice oil involved in the "Yusho" incident was contaminated with Kanechlor 400, a Japanese brand PCB containing 48% (by weight) chlorine. The various Aroclors (1016, 1242, 1248, 1254) are composed of mixtures of individual PCB molecules containing varying numbers of chlorine atoms. The data in Table 1 5/ shows the overlap in percentage occurrence of similar molecules containing the same number of chlorine atoms between Aroclors 1016, 1242 and 1248. The 48% (by weight)chlorine containing PCB, Aroclor 1248, is very similar to the PCB involved in the "Yusho" incident, Kanechlor 400. Consequently, the human data derived from the "Yusho" incident, although stemming from exposure to a Japanese PCB, are relevant and significant in establishing a temporary tolerance for PCBs of the American variety.

The victims in the "Yusho" incident were calculated to have consumed, on the average, 15,000 milligrams/day of the Kanechlor 400 contaminated oil. The oil itself was contaminated at levels of 2,000 - 3,000 ppm PCBs, the

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4/ See Footnote 2.

5/ See Table 1.

average level of PCB contamination in the oil being 2,500 ppm. The levels of PCB contamination of the oil were calculated by comparing the known organic chlorine content of the rice oil with the known organic chlorine content of Kanechlor 400.

Using the two average levels (consumption of rice oil and PCB level in the rice oil), the average daily intake of PCBs was estimated to be 37.5 mg/day. The average cumulative dose of PCBs causing an overt effect in the Japanese victims was reported to be 2,000 mg. Based on the average daily intake of 37.5 mg/day, it would take 53 days of exposure to consume this amount. The period of exposure no doubt varied around this figure. However, we estimated the maximum exposure time to have been 100 days.

TABLE I

Approximate Composition of Aroclor 1242 and 1248

Chlorine Atoms	Wt. % Cl/molecule	Aroclor 1016	Aroclor 1242	Aroclor 1248
		%	%	%
1	18.6	(1)	3 (0.7)	
2	31.5	(20)	13 (16)	2
3	41.0	(57)	28 (49)	18
4	48.3	(21)	30 (25)	40
5	54.0	(1)	22 (9)	36
6	58.7	(<0.1)	4 (1)	4

Adopted from : Env. Res. 5:262 (1972)

Data from Thurston, PCB Newsletter, No. 3, July 1971. Numbers in parentheses represent values reported by Monsanto.

Humans in the United States have not been exposed to PCBs at concentrated levels as occurred in the "Yusho" incident. PCB exposure in the United States

has been sporadic and self-limiting in nature, as far as the general public was concerned. Accordingly, in developing temporary tolerances based on the data from the "Yusho" incident, a time period of 1,000 days of exposure to PCBs was used. As previously stated, this was not an analysis based on lifetime exposure. Rather, it was postulated that PCB levels in food would steadily decrease over the 1,000 day time period used in the calculation. The sporadic and self-limiting exposures in the United States were generally thought to result mainly from contaminated animal feed. As measures were adopted to prevent future contamination, the PCB level in food was expected to be reduced.

In calculating a total allowable exposure from the average overt dose in the "Yusho" incident, a safety factor of 1 to 10 was used.[6/] A total allowable exposure of 200 mg was calculated. Because of the sporadic and self-limiting nature of PCB exposure in the United States, the total exposure (200 mg) was spread out over the 1,000 day time period, providing a tolerable daily exposure of no more than 200 micrograms per day. Transforming this figure to a body weight, per day figure for a 70 kg adult produced a figure of three micrograms/kg body weight/day. Adults should not be exposed to greater amounts on a daily basis.

6/ Classically, when using human data, the 1/10 factor is applied to a no-effect level to determine an allowable level of exposure. This was not, however, the first time that the factor was applied to an effect level. In 1969, for example, the 1/10 factor was applied to an effect level in setting guidelines for mercury in fish.

Q. Are children more susceptible to PCBs than adults?

A. Infants and young children are more susceptible to toxicants, such as PCBs than adults. They also consume a greater amount of food per kilogram of body weight and therefore have a proportionately greater exposure to PCBs than do adults. Therefore, in calculating the temporary tolerances, it was appropriate to use an additional safety factor with respect to infants and young children. Accordingly, the acceptable daily exposure for children was calculated using the lowest total dose producing an adverse health effect.

Data from the "Yusho" incident established that the lowest total dose producing an adverse health effect was a total of 500 mg PCBs. Using the 1/10 factor spread out over 1,000 days, the tolerable daily exposure is 50 micrograms per day. Infant and young children should, therefore, not be exposed to PCBs at a level greater than one ug/kg body weight/day.

Q. Could you give a few examples of the amounts of different types of foods which contain PCBs at the tolerance level and the dose received by ingesting each?

A. Consumption of the following foods containing PCBs at the tolerance levels would result in the indicated intake:

Food	Serving	PCB Guideline	PCB Ingestion
Chicken	250-300 gm	5 ppm fat (0.5whole)	125-150 mcgs
Dairy Product	10 gm butter (80% fat)	2.5 ppm fat	20 mcgs
	50 gm cheese (25% fat)	2.5 ppm fat	31 mcgs
Milk	800 ml.	2.5 ppm fat	80 mcgs
Two eggs	100 gm.	0.5 ppm	50 mcgs
Fish	100 gm.	5 ppm	500 mcgs

Q. Is there a wide margin of safety in the 5 ppm PCBs limit in fish?

A. In the case of PCB contamination of fish, it is quite obvious that the 5 ppm tolerance provides a low margin of safety in restricting the consumer's daily intake of PCBs to less than 200 mcg. However, for most people, this margin of safety is considered adequate, based on FDA data on the incidence and levels of PCBs in fish. For example, in 1973 FDA conducted a rather extensive survey of PCB levels in fish that are of commercial significance. A total of 600 fish samples of various species were examined under the survey. Eighty-eight percent of these samples had no more than trace amounts (less than 0.24 ppm), while less than 1% of the samples contained PCBs above 5 ppm.

However, based on reports from the New York State Department of Environmental Conservation, as well aa data generated by FDA's New York Field Office, the situation with respect to the incidence and levels of PCBs in fish from the Hudson River is not typical of the national data collected by FDA in 1973. It is for this reason that FDA is extremely concerned about the problem of PCBs in Hudson River fish since the regular ingestion of fish containing PCBs above 5 ppm represents a potential public health problem with unknown long-range consequences.

Q. Has the FDA ever enforced these regulations?

A. FDA has jurisdiction over food only when it is offered for shipment or shipped in interstate commerce. In the case of fish, we have found shipments of carp and other species which originated in waters from the Great Lakes Region that exceeded the temporary tolerance of 5 ppm of PCBs. As a result, we have initiated seizure action of the violative fish. Shippers of such fish are also, in appropriate cases, liable to criminal action or can be enjoined from future shipments.