FOOD, ANYONE?

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"I'd hate everybody to start worrying about the eggs they eat." This comment to the press by a spokesman for the Food and Drug Administration, made after learning that FDA had permitted more than 60,000 eggs contaminated with a DDT-like toxic chemical to be consumed by the public, speaks volumes about the Government's protection of the food supply. Nine months later, still another such "accident," necessitating the destruction of more than 1.2 million chickens, confirms that food consumers remain at the mercy of the fertile creativity of the chemical industry.

According to the President's Council on Environmental Quality, several thousand new chemical compounds are discovered each year, of which several hundred are annually introduced into commercial use. Many of these are intended for use as food additives. Many, however, are poisons expressly prohibited by law from coming into contact with humans, much less entering the food supply.

Polychlorinated biphenyls (commonly known as PCBs) are compounds of the poisonous variety. FDA requires that meat or fish contain PCB residues no more than five parts per million (ppm) and that eggs have no more than 0.5 ppm. PCBs possess toxicological, chemical, and environmental properties strikingly similar to DDT. In fact, the compounds are so similar that much of the environmental damage attributed in the past to DDT is now thought to have been caused by PCBs. The Monsanto Company, a giant chemical firm, is the sole domestic manufacturer of PCBs (under the name Aroclor). They are used widely as industrial chemicals in heat absorption and plasticizing processes, principally in heat transfer units, electric transformers, and the like.

Like DDT and many other chlorinated hydrocarbons, PCBs are extremely persistent, pervasive, and toxic substances. They degrade even more slowly than DDT, and are water insoluble and fat soluble. Thus, PCBs accumulate and concentrate in the body's fatty tissues. In addition to (and in part because of) their stability, PCBs are found virtually everywhere in the ecosystem. In 1970, PCB levels in fish near England were found as high as 900 parts per million—"the highest concentration of poisonous industrial chemicals ever found in wildlife," according to a British government study. One researcher reports that in Arctic lakes, rarely if ever visited by man, all of the fish analyzed contained measurable amounts of PCB; one lake trout had twelve ppm in its fat. Concentrations of up to 600 ppm have been found in human tissues. And random samples of milk from nursing mothers in California averaged higher than two ppm.

The incomplete scientific evidence on PCBs suggests that they constitute a significant human health hazard. Since PCBs were first recognized as an environmental problem only in 1966, and since the methodology for distinguishing PCBs from DDT and other chlorinated hydrocarbons has been developed only in the last few years, scientific data on the nature and extent of PCB toxicity for humans is necessarily quite limited. The prevailing view among PCB researchers, however, is that the chemical can affect liver detoxification activity, enzymatic processes, and other basic biological functions.

Back in 1942, all 100 men in continual work contact with PCBs in one plant contracted chloracne, a skin disease. Cases of yellow liver atrophy in humans have also been attributed to PCBs. In 1968, cooking oil contaminated with PCBs caused an outbreak of skin disease affecting more than 300 people in Japan, including nine pregnant women. Some of the women miscarried, and all (including the babies) showed and continue to show symptoms of chlorobiphenyl poisoning. According to the rough calculations of Dr. Robert Risebrough, a PCB expert at Berkeley, consumption of forty-five pounds of fish and/or poultry contaminated

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with PCBs at the FDA-approved level of five ppm might produce the effects observed in Japan. There is evidence that the toxicity of PCB formulations may in fact be attributable to the presence of contaminants (called dibenzofurans) similar to and only slightly less toxic than the contaminants (called dioxins) of 2,4,5-T, the herbicide widely used in Vietnam (under the name Agent Orange) and cancelled for use on food crops in the United States.

There has been no lack of warnings about the human hazards associated with the widespread industrial use of PCBs. In April, 1970, Representative William F. Ryan, New York Democrat, called on FDA to set formal food tolerance levels for PCBs and convene an interdepartmental task force to study the problem. Ryan has also introduced legislation to ban PCBs until Monsanto can prove their safety. Yet FDA has never established a formal tolerance for PCBs in food. After several incidents of massive PCB contamination of the food supply, FDA finally set an arbitrary, temporary "action level" of five ppm in flesh and 0.5 ppm in eggs, below which PCB residues were deemed "safe."

Between April 30 and mid-July of 1971, PCBs used as heat transfer fluid leaked into fishmeal produced at a North Carolina plant. The meal was sold to sixty-five companies in twelve states for use, among other things, as an ingredient in feed for chickens, turkeys, hogs, and catfish. When *Holly Farms*, the nation's largest producer of broiler chickens, discovered in June that flocks fed this feed showed mortality about seven times the normal rate, FDA (responsible for inspection of shell eggs) and the U.S. Department of Agriculture (responsible for inspection of meat, poultry, and egg products) found themselves with a full-scale food crisis on their hands. In the ensuing weeks, these agencies condemned many tons of fishmeal, more than 165,000 broilers, 250,000 pounds of turkeys, hundreds of thousands of eggs, several hundred thousand pounds of egg products, a thousand tons of catfish feed, and other assorted foodstuffs. This flurry of activity prompted many press releases by these agencies and Monsanto, congratulating themselves on their unremitting protection of the consumer and assuring him of the complete wholesomeness of his food.

Neither the self-praise nor the assurances were justified; indeed, quite the reverse was the case. The agencies were slow in gearing up their systems for sampling products exposed to contamination, and these sampling systems were generally not adequate for contaminations of this magnitude. The peculiar division of inspection responsibilities was exacerbated by a striking lack of coordination among the agencies. For example, FDA never furnished USDA with a list of the subcontractees of the sixty-five firms which purchased the contaminated meal; thus USDA could never ensure that all possible sources of contamination of meat and poultry were closed off. Perhaps most important, the public was kept in the dark.

These and other regulatory failures by the food agencies *are not* simply the consequences of limited resources. For fiscal 1972, Congress appropriated $6 million *more* for meat and poultry inspection than USDA requested. Congress has, in recent years, also tended to give FDA at least as much as FDA requests for food inspection activities. One's answer to the key question—how much money is "enough"?—in large part depends on the manner in which the agencies view and discharge their public trusts.

These failures, then, are really symptomatic of a more fundamental problem—the regulatory philosophy which seems to pervade the food agencies. Judging from the incident of the PCB-contaminated fishmeal, one can identify three elements of this philosophy —the reasonable risk principle, the secrecy principle, and the mindless public principle.

Throughout this incident, the food agencies bombarded the public with assertions that since absolute safety was an impossible goal, reasonable risks must be taken if society is to reap the benefits of PCB use. Standing by themselves, such assertions are unexceptionable—benefits and costs must of course always be weighed. In the case of environmental chemicals like PCBs, however, FDA's assurances are presumptuous and misleading. As Dr. Samuel Epstein of Case Western Reserve Medical School has testified: "When one talks about matching benefits against hazards, that implies that you have a clear concept of what the hazards are and a clear concept of what the benefits are. In the absence of such information is it possible to deliver a reasoned analysis on the way these factors match?"

While the industrial benefits of PCBs have been identified, there has been no showing that a nonhazardous alternative of equal or greater efficacy does not exist or could not be developed. And, as we have seen, the cost side is uncertain at best, with some evidence of long-term food hazards all along the food chain. Whatever result a comprehensive benefit-cost analysis might yield, it is quite clear that FDA has not conducted such an analysis. Quite the contrary. According to Dr. Risebrough, the five ppm figure "is just a number. I'm sure FDA pulled it out of the air." Some other toxicologists inside FDA agree. And recent events strongly suggest that FDA does not even enforce these levels with any seriousness.

The agencies' adherence to the reasonable risk principle might explain what otherwise seems inexplicable —the toleration of *any* levels above a trace of this toxic substance in the food supply. Yet the explanation given by a deputy associate commissioner of FDA to an interagency meeting of scientists makes one wonder how principled and considered this toleration is:

"I think I will start off by giving the FDA regulatory policy on PCBs in foods. It is a very simple one: we do not approve of any foods containing PCBs, nor do we condone any practices which result in any levels of PCB residues in foods.

"While that may be our policy, until there are some legally sanctioned uses, we have been forced to compromise that policy to the extent that we do not object to the marketing of certain specific lots of food that might contain some low levels of PCBs. I do want to stress the difference between approving and not objecting to. I think this is the key."

FDA's permissiveness was fortified when Monsanto, after another earlier PCB scare, agreed to market PCBs only for "closed system" uses, that is, uses not leading to human exposure. Yet this theory crumbles under scrutiny. First, Monsanto does not and cannot control the uses to which its purchasers put PCBs; it can suggest but it cannot coerce. Second, until recently, and despite almost two years of constant prodding by Representative Ryan, Monsanto arrogantly and persistently refused to disclose any of its PCB sales data to the Government, regarding such data as "extremely confidential" (although it has no domestic competitors for the product). Thus, there was no way for anyone else, including the Government, to enforce this limitation or evaluate the hazard to the public.

At least as recently as last June, PCBs were being widely employed in "open system" use, as a constituent of carbonless carbon paper and as an ingredient of much recycled paper, at levels up to 30,000 ppm. Only in September did the public learn that FDA had known this since June. Finally, a truly "closed" system is about as rare a phenomenon in modern life as truly clean air. Significantly, *all* known incidents of PCB contamination of food have resulted from so-called "closed system" uses, such as in industrial plants, plastic packaging, silo linings, and heat transfer units.

A fundamental objection to the reasonable risk principle, as implemented by the food agencies, is that it is constantly thwarted and nullified by a competing dogma—the secrecy principle.

If reasonable risks must be taken, then the public and Congress are entitled to participate in the judgments as to what risks are reasonable, what level of safety the public is willing to pay for, and what priorities are to be served. The agencies' passion for secrecy, however, precludes such public inputs by denying the public information necessary to making such judgments. The PCB incidents abound with instances of this secrecy.

An egregious case occurred in August when FDA took samples from a suspect shipment of 60,000 eggs in North Carolina, releasing the shipment for trucking to a Washington, D.C., distributor. Five days later, when FDA completed its analysis of the sample, it found PCB levels in the sample of four to five times the permissible concentration. FDA went to the distributor's warehouse, only to learn that the eggs had been sold to Washington area restaurants several days earlier. At this point, FDA threw up its hands and went on to other things. FDA not only failed to make any effort to alert consumers to the danger so that they could destroy those contaminated eggs not yet consumed. It also threw a cloak of secrecy over the incident.

The matter began to public only when an outside investigator leaked it to the press more than a week later. FDA, asked by the press to explain its performance, proceeded to undermine the integrity of its own "action level," established in light of the chronic toxicity of PCBs, their concentration in human tissues, and their ubiquity in the ecosystem. One FDA spokesman told the press, "That much PCB is like a drop in a tank car." Another insisted that there was no real health problem because of the short term exposure. "I'd hate everybody to start worrying about the eggs they eat."

Unfortunately, this was not an isolated example of the secrecy principle in action. On August 12, 1971, outside investigators learned that twenty of the first fifty-six egg samples tested by FDA throughout the southeast producing areas had contained excessive levels of PCBs and that this had been known by FDA for more than a week. Again FDA failed to make its findings public, despite FDA's knowledge that 60,000 tainted eggs had already reached consumers, and despite the distinct possibility that other contaminated eggs were likewise reaching consumers. Again, only news stories following a leak to the press induced FDA to issue a belated press release.

USDA also honors the secrecy principle. USDA, on August 12, discovered in turkeys the highest PCB levels theretofore found in meat or poultry products en route to the consumer market: 11.83 ppm in total edible tissues. Although USDA detained 250,000 pounds of turkeys as a result, it failed to make this matter public until it was obliged to respond by letter to inquiries made by Senator George McGovern. On August 26, the day of its letter to McGovern, it finally issued a news release.

These instances of non-disclosure—when they are ultimately brought to light—erode public confidence in food inspection agencies. Perhaps more important, these agencies, by inhibiting the public and Congress from learning of the magnitude of the threat of chemical contamination of the environment, weaken the inclination of the public to press for changes in public policy concerning food inspection and toxic substances.

Supplementing and legitimizing the reasonable risk and secrecy principles is the mindless public principle. FDA Commissioner Charles Edwards elucidated this principle with admirable clarity in testimony before the Senate Appropriations Committee on May 13, 1971. After speaking of the "far more sophisticated consumer today," a consumer who is far more knowledgeable about scientific theory and techniques, who "wants more information about the product he buys," Dr. Edwards continued:

"We can't caution the public that there might be something wrong with a product in rare instances or that use of a product should be restricted, because

public reaction is always an *ov* :action; the pendulum swings too far in most cases, and consumers tend to boycott a product if any doubts have been raised about it, even though we might feel that continued use within certain limits is entirely justified." (Dr. Edwards' emphasis.)

Is the "far more sophisticated consumer today" really so mindless? Consider the recent discovery of botulism in a small number of cans of Campbell's chicken vegetable soup, and the publicized recall of the soup. Surely, in view of the widely publicized death and paralysis of a man and wife from Bon Vivant soup last summer, this is an excellent case with which to test Dr. Edwards' thesis that "public reaction is always an *over*-reaction." According to *The New York Times* of August 25, however, the public reacted with great circumspection. A spot check in some fifteen cities revealed that consumers were taking the crisis calmly, that the public disclosure of the recall had little effect on soup sales. Some shoppers made inquiries of their grocers and "a few wary" ones returned cans of Campbell's chicken vegetable soup, but calm was the prevailing response.

A food inspection agency cannot justifiably fail to make full and timely disclosure about the quality of the food supply on the ground that an informed public will always over-react. Our system presupposes that, within broad limits, it is for the consumer to decide for himself on the basis of full information what he will and will not eat, and what risks he will and will not take.

Nor is there justification for failing to inform fully the consumer on the ground that the danger to the public is not yet conclusively proved. When dealing with the integrity of the food supply, agencies cannot act on mere rumor, to be sure, but neither in most cases can they afford to wait until all the evidence is in. Of necessity, they must often act on the basis of incomplete information and disclose that fact to the consumer. The burden of any uncertainty must not fall on the consumer. The food inspection laws did not intend that he be made a guinea pig simply because we live in an uncertain world.

It is important to bear in mind that the regulatory philosophy implicit in the reasonable risk, secrecy, and mindless public principles could not flourish if the administrators of the food agencies were subjected to a truly pluralistic array of pressures in their day-to-day decision-making processes. They are not. The pressures —in the forms of information, the claims of personal ties, relentless lobbying, campaign contributions, and other instruments of persuasion—are virtually all from producer and marketing groups. Input from consumers is sporadic and poorly financed. The existence of "advocacy gap" has been documented for both USDA and FDA by recent Nader reports on those agencies (*Sowing the Wind* by Harrison Wellford and *The Chemical Feast* by James S. Turner).

Since the Washington, D.C., contaminated eggs incident, several new "isolated occurrences" (in USDA's phrase) of PCB contamination of food have come to light. In Minneso' 50,000 turkeys, conta minated at levels as high as thirty-five ppm in edible tissue, were processed by a subsidiary of Swift & Co., the world's largest meat packer. Swift's identity was concealed by high USDA officials "in the best interests of consumers" and "because the situation now is under control." Yet many months later, the source of contamination remains a mystery. Nevertheless, USDA tested these turkeys to see if they could be "cooked out" until the PCB levels fell below five ppm, at which point they could be salvaged and marketed for use in frozen dinners, pot pies, and soups. Swift & Co., apparently more sensitive than USDA to the ensuing outcry, subsequently announced that the turkeys would be destroyed after all.

Subsequent events are even more ominous. Excessive PCB residues have now been found in many food packaging materials, raising the specter of PCB migration from such packaging to the food itself. And the preliminary results of a Cornell study of ring doves fed PCBs found that no ill effects in the first generation were followed by heavy embryonic mortality in the second, suggesting (in the researcher's words) that "the current interim guideline of five ppm does not have the margin of safety that earlier single-generation studies had suggested."

If one looks diligently, very diligently, for a hopeful portent in all of this, there is one possible solace. Evidently, FDA and USDA *can* learn from their mistakes after all—at least if those mistakes recur often enough. In mid-February, yet another "isolated" PCB emergency was made public, this time in Maine. The magnitude of this latest contamination is truly staggering. In late March, with more poultry being condemned every day, USDA had already destroyed a total of 1.25 million broilers and roasters—over four million pounds of poultry. The initial response from the food agencies was that no more than 250,000 birds could possibly be contaminated, that they had identified the source of contamination, and that everything was under control. They now concede, however, that they know neither the source nor the extent of contamination, and that they cannot be certain that none reached consumers. In a classic case of too little too late, FDA has finally proposed regulations to ban the use of PCBs in feed mills, food processing establishments, and in food packaging facilities, a proposal that FDA was supposed to have implemented many months ago, long before the Maine incident. While this is a small step forward, to be sure, this proposal will not affect PCB contamination of the food chain from other sources, nor will it affect FDA's liberal tolerances of PCBs in foods.

At a press conference called by FDA Commissioner Edwards to reassure the public about PCBs, Edwards insisted that "an outright ban is not feasible and would not be in the best interest of the consumer." He was visibly shaken when informed by a member of the press that a limitation on PCBs had been in effect in England for some time.