FOOD SAFETY AND PUBLIC HEALTH

Interaction of Science and Law in the Federal Regulatory Process

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The programs of the Food and Drug Administration (FDA), which operates under a broad mandate of regulatory authority provided by the Congress in the form of the Food, Drug, and Cosmetic Act, demonstrate the way in which science and law interact to protect public health through the regulatory process. In particular, sections 402, 406, and 409 of the Act provide the means for regulating both new and old food products approved for use by the petition process as well as foods which present a potential hazard because of environmental accidents which result in residues of undesirable or dangerous chemical substances. The episodes of foods contaminated with polychlorinated biphenyls (PCBs) or polybrominated biphenyls (PBBs), and the manner in which action levels or guidelines were developed to regulate the allowable levels of these chemicals in foods, describe the pragmatic way in which FDA protects public health by restricting the allowable levels of chemical substances in foods.

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IN DESCRIBING THE ROLE of the Federal government in food safety and the use of the regulatory process in public health protection, several items should be placed in the context of how science and law interact to enhance or protect public health. In particular, the programs of the Food and Drug Administration (FDA) may serve as a demonstration of how science and law are interrelated in the regulatory process.

Humans ingest or are exposed to a variety of substances that are under the regulatory control of FDA, such as foods, food additives, color additives, drugs, vitamins, and minerals; residues found in animal feed such as animal drugs, and pesticides; and even cosmetics. The statutes and regulations used by FDA to control these substances vary with the form of ingestion or exposure, and the kind, amount, and length of exposure to these substances.

The statutes referred to below originate from the Federal Food, Drug, and Cosmetic Act[3] as amended, Title 21, United States Code (copy dated October 1976). Regulations are quoted from Title 21, *Code of Federal Regulations* (CFR), Chapter 1. Unless otherwise noted, section references are to the statutes.

In describing the regulatory activities of FDA, several definitions from the CFR are needed. These include the definitions for food, food additive, and color additive.

A. The term *food* means: 1) articles which are used for food or drink for man or other animals, 2) chewing gum, and 3) articles which are used for components of any such article.

B. A food additive is any substance:—The intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.

(i) A food additive under law is thus not simply anything added to food. Certain substances that are added to foods are exempted from the statutory provisions relating to food additives but are still subject to the other provisions of the Act (such as section 402, the section on adulterated foods). The definition of a food additive is restricted to substances "not generally recognized . . . to be safe under the conditions of its intended use." (This qualification is the basis for the Generally Recognized As Safe (GRAS) List.) The section then continues: "except that such term (*food additives*) does not include: 1) a pesticide chemical in or on a raw agricultural commodity; or 2) a pesticide chemical to the extent that it is used in the production, storage,

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or transportation of any raw agricultural commodity; or 3) a color additive; 4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act . . . or (other Acts). [This last clause is the so-called "prior sanction" clause.] 5) a new animal drug."

(ii) Thus any substance which fits the definition of a food additive given above and which is not on the GRAS list, for which "prior sanction" has not been granted, or which does not fit any of the other excluded categories is a food additive and is specifically subject to regulation under section 409 of the Act.

(iii) Any substance that is a food additive is also a food and subject to other provisions of the Act.

C. A color additive is a material that: 1) is a dye pigment, or other substance made by a process or synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; and 2) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof is capable (alone or through reaction with other substances) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

General Food Safety

Since FDA's inception, its regulatory decision-making process has operated under a broad statutory mandate given by the Congress. The Food and Drug Act of 1906 prohibited the use in food of any added poisonous or other added deleterious ingredient which may render the food injurious to health. The Federal Food, Drug, and Cosmetic Act of 1938 states that a food may not contain any poisonous or deleterious substance which may render it injurious to health.

The Food Additives Amendment of 1958 requires the FDA to consider safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, may be adequately tested by animal experimentation. The Drug Amendment of 1962 states that safety must be shown by adequate tests and by all methods reasonably applicable to show whether or not such a drug is safe for use.

In general, safety testing depends upon the fact that, as the exposure dose is decreased, toxicity effects also decrease and a dose is finally established at which "no effects" are produced. Usage levels which are permitted in food are then set, based on the no-effect level in which an additional safety factor has been incorporated.

To some extent the kinds of safety data required by a preclearance review to establish the safety of a proposed food or color additive are also directly related to the anticipated degree of human exposure likely to result if such use is permitted. For significant direct additives, review to establish the safety of a proposed food or color additive is also directly related to the anticipated degree of human exposure likely to result if such use is permitted. For significant direct additives, *i.e.*, those which are intentionally added to food, a complete toxicological workup is required. For indirect additives, *i.e.*, those which have potential for transfer into foods by virtue of their use in the manufacture or maintenance of food packaging materials and processing equipment, toxicity testing requirements may be reduced. Specifically, only short-term animal testing might be required to determine if a substance is highly toxic when essentially no residues from migration or extraction are expected to occur in food.

At present, a complete toxicological workup includes a variety of chemical tests to determine the composition and purity of the substance in question, followed by a variety of experiments in test animals to determine the quantitative strength of all toxic effects that the substance can be demonstrated to cause in animals receiving large daily doses over extended periods of time. For example, lifetime feeding studies are required in two rodent species—usually the mouse and the rat. These tests are designed to establish an "effect" level, if possible. FDA looks for a variety of effects, such as poor growth and development and visible signs of neurological abnormalities, including those likely to be associated with chemically induced lesions of the motor and sensory centers and pathways of the nervous system. Animals are observed for abnormalities of gait, righting reflexes, ingesting reflexes, and tremors. They are also observed for any other visible palpable signs of disease such as skin, ear, and eye abnormalities, gastrointestinal disturbances, and tumors. After death, the animals are subjected to a complete autopsy and extensive histopatho-

logical examination to determine the cause of death, the presence or absence of diseases related to the compound, and any incidence of tumors including malignant neoplasms (cancer). The data are analyzed statistically when differences between test and control animals are seen, to determine the statistical significance of those observed differences. One rodent lifetime study, the rat study, is designed so that the animals used have been exposed to the test material over their lifetimes, beginning with exposure to any substance likely to cross the placenta. In multigeneration studies, parents of successive generations are observed for reproductive performance and fertility, and the offspring, for viability and growth. Successive mating serves to determine whether offspring that were exposed *in utero* are capable of reproducing their own normal offspring. The multigeneration reproduction studies (in most cases in the rat) usually involve two litters per generation over three generations.

Other specific tests, such as teratology studies, are performed to see if a substance can be demonstrated to be capable of inducing birth defects. Reproductive testing, in general, will detect decreased fertility, increased fetal death and birth defects, decreased survival and well-being of offspring at birth after being exposed *in utero*, and abnormal growth and development during the lactation stage with the maternal animals still exposed to the test substance. These required reproduction protocols will obviously measure effects of the substance tested on the entire spectrum of physiological functions involved with the maternal animals still exposed to the test substance, and on the entire spectrum of physiological functions involved with reproduction. The physiology of reproduction involves the integration of complicated metabolic, hormonal, neurological, and behavioral processes and thus serves also to detect more subtle disturbances of higher centers.

REGULATION OF CARCINOGENIC SUBSTANCES

Federal authorities to regulate carcinogenic substances are usually contained within statutory provision for regulating toxicity in general. With two major exceptions, the relevant statutes do not specifically mention carcinogenicity or cancer. These exceptions are the Federal Food, Drug, and Cosmetic Act and the Toxic Substances Control Act. Both Acts contain provisions that relate directly to carcinogens, and both specify procedures for regulating carcinogenicity that are distinct from those for general toxicity.

Nine statutes are important in the regulation of substances. One of these, the Food, Drug, and Cosmetic Act, generally takes precedence over other Federal laws for the carcinogenicity of substances that may be ingested. Health hazards in the workplace are covered by the Occupational Safety and Health Act. A third class of substances, those to which consumers are likely to be exposed (other than foods, drugs, cosmetics, and other excluded substances), is regulated by the Consumer Product Safety Act and the Federal Hazardous Substances Act. Four statutes administered by the Environmental Protection Agency cover specific areas of the physical environment: the Clean Air Act; the Water Pollution Control Act; the Safe Drinking Water Act; and the Federal Insecticide, Fungicide, and Rodenticide Act. The Environmental Protection Agency also administers the Toxic Substances Control Act, a law which was designed to fill in the gaps in the regulatory coverage of toxic substances in the environment.

Of these laws, only the Food, Drug, and Cosmetic Act contains a provision such as the Delaney Clause that will allow no regulatory discretion. When a substance regulated by this clause is found to be a carcinogen, it must be banned. No other law mandates such specific obligatory action to ban.

The various laws also differ in their approaches to risk/benefit analysis. Some, such as the Toxic Substances Control Act, explicitly require the balancing of health risks against economic and other public impacts of regulation. Others permit such analysis but do not require it. The Food, Drug, and Cosmetic Act requires it in some cases and forbids it in others, depending on the type of substance in question.

Several sections of the Act provide some specific examples of the regulatory role FDA plays in the area of food safety. These include sections 301, 402, 406, 408, and 409 of the Act.

Regulation of Food Additives: Section 409

A. Once a substance is classified as a food additive under the strict meaning described above, it is deemed unsafe for the purposes of section 409 unless it has been exempted for investigational use, or unless a regulation issued under this section prescribing the condi-

tions under which such additive may be safely used is in effect and the additive and its use or intended use are in conformity with the regulation.

In either case, the food additive is not in violation of section 402 of the food adulteration section, which serves as the basis for prohibiting use.

Under the Delaney Amendment, the regulation is not to be issued if a fair evaluation of the data fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe. The Amendment specifies that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests that are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. This provision does not apply to the use of a substance as an ingredient of feed for animals that are raised for food production, if the Secretary finds (i) that, if under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

If a regulation is issued, FDA may set tolerance limits, and specify the foods in which the food additive may be used and in what amounts, labeling instructions, etc.

In determining whether a regulation shall be issued, the following factors (as well as any other relevant items) shall be considered: 1) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive; 2) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and 3) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data.

B. Before the food additive is marketed, the petitioner has the burden of proof to show that the proposed food additive is safe and performs as claimed. However, once a food additive is on the market, with an approved regulation, a change occurs. Although the burden of proof remains with the original petitioner, the burden of "going forward" with the evidence shifts to FDA. That is, FDA has the responsibility for presenting evidence that will lead to a reconsideration of a food additive's safety. Under the Delaney Clause, FDA must exercise its responsibility as soon as it finds that a food additive is carcinogenic. When FDA proceeds under the general safety clause, it must present evidence that the food additive has been shown to have certain effects (*e.g.*, toxicity) and that these effects lead to harm. The general safety clause is the portion of section 409 that precedes the Delaney Clause.

C. Action against food additives deemed unsafe is taken on the basis of section 402, which covers adulterated foods.

Regulation of Environmental Contaminants in Food

There is little question that the decision-making process for regulatory activities dealing with safety issues is a difficult and often unappreciated effort. The scientific uncertainties that exist today often require that questions of safety be answered without the benefit of an adequate scientific data base. This is particularly true in the case of environmental contaminants where human exposure has never taken place before and where even the animal toxicological data may be scarce if it exists at all.

Much of the information concerning the toxicology of various chemical substances has been obtained from experiments in animals. In general, safety testing depends upon the fact that as the exposure dose is decreased, toxicity effects also decrease and a dose is finally established at which "no effects" are produced. Such dose–response relations are central to the study of toxicology in animals and should be of equal concern in man's exposure to a variety of environmental and other insults. However, such dose–response relations in man must be established or identified with a great deal of care and caution. Outcome may vary greatly in significance: at one extreme, death; at the other, a change in physiological or psychological function. The weight that should be given to each in the utilization of data for formulating regulatory policy may vary greatly.

Three sections of the Act are applicable in the regulation of environmental contaminants in food. These are sections 301, 402, and 406.

A. Section 301 of the Act prohibits the introduction of any adulterated or misbranded food into interstate commerce. It also prohibits the adulteration or misbranding of foods already in interstate commerce.

B. Section 402 lists the criteria by which a food is to be deemed adulterated. The following excerpts from section 402 are of particular interest for this report. A food is deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or if it bears or contains any added poisonous or added deleterious substance (other than one which is a pesticide chemical in or on a raw agricultural commodity, a food additive, a color additive, or a new animal drug) which is unsafe within the meaning of section 408; or if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409 provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512.

C. Section 406 states, "Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of . . . section 402(a); but when such substance is required or 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 any quantity exceeding the limits so fixed shall be deemed to be unsafe for purposes of the application of . . . section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of . . . section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food, the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances."

Application of Regulatory Authority

Several of the current problems in environmental contamination involve a group of chemicals consisting of halogenated biphenyls, and the regulatory action taken against these chemicals illustrates the use of sections 301, 402, and 406 of the Act in public health protection.

During the 1960's numerous silos were constructed in the Midwest using concrete blocks as the masonry material in the construction and a polychlorinated biphenyls (PCB)-containing material as a sealant to retain moisture in the silo. After a period of several years, the sealant began flaking off into the silage which, in turn, was consumed by dairy cattle, resulting in residues of PCBs in processed milk. In view of the avoidability of this source of contamination in processed milk, FDA considered the milk adulterated under section 402 and any detectable residue resulted in seizure of the products.

In contrast, an example of PCB contamination that is essentially unavoidable is illustrated by the PCB contamination of fresh water lakes and streams, which resulted in PCB residues in fish caught in these contaminated waters. The handling of this type of contamination problem illustrates the use of section 406 of the Act and, to a large degree, the kind of regulatory decision making that FDA expects to see most frequently with environmental contaminants, *i.e.*, the establish-

ment of guidelines or action levels for residues of chemicals in various foods. This particular exercise also allowed the use of human epidemiological data in determining allowable residues, a data source not often available in such determinations.

In 1968, an unknown number of individuals were exposed to Kanechlor 400, a PCB manufactured in Japan, as a result of consuming rice oil (Yusho) containing PCB residues which resulted from contamination of the rice oil with fluid from a heat exchange unit.[2]

The typical clinical findings included chloracne and increased pigmentation of the skin, increased eye discharge, transient visual disturbances, feeling of weakness, numbness in limbs, headaches, and disturbances in liver function. Most of the babies born to mothers with Yusho had skin discoloration which slowly regressed as the children grew. Adult Yusho patients had protracted clinical disease with a slow regression of symptoms and signs, suggesting a slow metabolism and excretion of PCB in humans, probably resulting from a long biological half-life.

It was estimated that individuals exposed in the Yusho incident consumed, on the average, 15,000 mg of the Kanechlor 400-contaminated oil. The oil itself was contaminated at levels of 2,000–3,000 parts per million (ppm) PCBs, with the average level of PCB contamination in the oil being 2,500 ppm. The level of PCB contamination of the oil was calculated by comparing the known organic chlorine content of the rice oil with the known organic chlorine content of Kanechlor 400.[2]

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, it was estimated that the maximum exposure time was 100 days.

Humans in the United States have not been exposed to PCBs at the high residue levels that 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, resulting in a total allowable exposure of 200 mg. 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 μg/day.* Transforming this figure and using an average body weight of 70 kg for an adult produced a value of 3 μg/kg body weight/day.

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

It was determined that the lowest total dose producing an adverse health effect was a total of 500 mg PCBs. Using the 1:10 safety factor spread over 1,000 days, the tolerable daily exposure is 500 μg/day. Infants and young children should, therefore, not be exposed to PCBs at a level greater than 1 μg/kg body weight/day.

An adult who consumes a balanced and varied diet would not be expected to ingest more than his tolerable daily exposure of 200 μg/day.

Similarly, an infant or young child consuming a balanced and varied diet would not be expected to ingest more than his tolerable daily exposure. However, it is conceivable, indeed foreseeable, that individuals whose diets are not well balanced and varied will exceed this allowable daily intake.

In addition to the human epidemiological data, other data from long-term animal studies (2 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. When data derived from dogs were used, a no-effect level of 2.5 μg/kg body weight/day was estimated. When rat data were used, the estimated no-effect level in man was 3 μg/kg body weight/day or a level similar to the human epidemiological data. Thus, for a 70 kg individual, an allowable level of PCB ingestion would be 175 to 210 μg/day.

Another example of the application of these sections of the Act, and one which illustrates the lack of, and need for, adequate animal and human data in an emergency involves polybrominated biphenyls (PBBs) as a source of environmental contamination in the state of Michigan.

In the late summer and fall of 1973, and continuing into early spring 1974, adverse health effects were observed in cattle in several dairy herds in the state of Michigan.[1] At that time, the cattle refused to eat manufactured feed; milk production decreased; the cattle lost body weight and developed abnormal hoof growth with lameness; cattle and swine aborted; and farmers reported the inability of heifers to conceive after they consumed manufactured feed.

Analysis of samples of the suspected feed revealed that the feed was contaminated with a flame retardant, hexabrominated biphenyls (HBB). Subsequent investigation revealed that a chemical company in Michigan manufactured both magnesium oxide, a dairy feed supplement sold under the tradename nutriMaster, and a flame retardant, hexabrominated biphenyl (HBB), sold under the tradename fireMaster, in this case, FF-1. Both of these products were distributed in brown paper bags with either "nutriMaster" or "fireMaster" stenciled across the top of the bag. When the top of the bag was torn off and discarded, identification was essentially lost. As the result of a mix-up in bags, fireMaster FF-1 was mixed with animal feed in place of the nutriMaster, apparently in the same proportion used for the nutriMaster.

It has been estimated that between the onset of contamination in the fall of 1973 and the establishment of the quarantine of affected herds and flocks in the spring of 1974, over 10,000 Michigan residents were exposed to PBB through the consumption of contaminated milk, meat, and other dairy products. A considerable amount of variation has probably occurred in both lengths and levels of exposure. As a group, the farm family members had been at greatest risk, followed by those individuals who purchased dairy products from contaminated farms on a regular basis. Some estimates of exposures of Michigan farm family members to PBBs are on the order of 5–7 g.

As a result of the lack of information on the toxicity of PBBs at the time of the contamination, the primary concern with the toxicity of PBBs revolved around the structural similarity to the PCBs. Since both human and animal toxicological data are available for the PCBs, it was felt that the initial work at FDA should concentrate on comparison of PBB and PCB effects in animals.

In studies at FDA comparing Aroclor 1254 and fireMaster BP-6 (HBB), some parameters tested showed no change with either chemical at any dose level. Other parameters were more sensitive to Aroclor 1254 than to fireMaster BP-6 and included decreased liver protein/g tissue, decreased liver RNA/g tissue, and depressed plasma glucose. Parameters more sensitive to fireMaster BP-6 included hepatomegaly induction, depletion of adipose tissue, increased percent liver dry weight, increased percent liver lipid, decreased liver deoxynucleic acid content, and decreased liver ribonucleic acid turnover measured at one point in time. All liver lipid fractions, including total fat, cholesterol, phospholipid, and neutral lipid, were increased more by fireMaster than by Aroclor.

The results of these tests indicated that PBBs caused greater responses at lower levels than did the PCBs and led to the conclusion that PBBs had the greater potential for biological activity, being as much as five times more active in a variety of parameters than were the PCBs. On the basis of these studies it was felt that regulatory action on the PBBs should be similar to that taken for the PCBs, but using an additional safety factor of ten to compensate for the fact that there seems to be a five-fold greater degree of biological activity. Therefore, FDA based its regulatory action on a 1,000-day exposure limit of 20 mg for PBBs, which translates to a limit average exposure of 20 μg per individual per day, or approximately 0.3 μg/kg body weight/day.

To reduce exposures to the minimum, FDA under authority of section 406 of the Food, Drug, and Cosmetic Act, established guidelines of 0.3 ppm on a fat basis in milk, meat, and dairy products and 0.05 ppm in animal feed and whole eggs.

As a practical example of the relationship of the acceptable daily intake to the FDA guidelines, let us assume that meat at the guideline level contains 10 percent fat for every 100 g of this meat consumed. The 10 g of fat present would contain no more than 0.3 ppm equivalent to 6 μg of PBBs per average serving of meat (200 g). Thus, even if a person consistently ate 3 meals of meat contaminated at the guideline level each day, the daily dose of PBBs would be 18 μg, which is less than the maximum "acceptable daily intake" that contains numerous built-in safety factors. Essentially the same situation would exist with milk. If milk containing about 4 percent fat is contaminated at the guideline level of 0.3 ppm, consumption of 1 liter of milk in one day would result in ingestion of 12 μg of PBBs.

While it is impossible to rule out the possibility that long-term adverse human health effects may result from exposure to PCBs or PBBs via the consumption of environmentally contaminated foods, no such illness related to PCB or PBB exposure in humans has been identified.

In summary, Congress has provided FDA with broad regulatory authority to protect public health by insuring a safe and nutritious food supply. The application of the intent of the Act rests with individuals who call upon science, law, and the regulatory process to accommodate the demands of safety, contamination, food requirements, Congress, consumers, and the courts. Perhaps, from time to time, the critics of this process should be offered the opportunity to participate in the decision-making arena in order to better appreciate some of these demands.

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