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Hearing Clerk
Department of Health, Education and Welfare
Room 6-88
5600 Fishers Lane
Rockville, MD 20852

Reference: Department of Health Education and Welfare
Food and Drug Administration
21 CFR Parts, 3; 121; 122; 128
Polychlorinated Biphenyls, Notice
of Proposed Rule Making
Federal Register, Vol. 37 No. 54,
Saturday March 18, 1972

Dear Miss McCullar:

As an interested person and private citizen, I wish to protest this proposal on the grounds that the course of action chosen by the Commissioner is not in concord with the authority granted him under the FD&C Act. However well intentioned the proposal and despite my whole-hearted agreement with his concern over the problem of contamination of food with polychlorinated biphenyls, I believe the objectives can be attained without doing violence to the FD&C Act. I am further of the opinion that the interests of consumers and producers can and must be protected within a framework of law and that it is the burden of the agencies of the Executive Department to act at all times within the authorities granted by the applicable laws of Congress.

Objection is taken to the proposals for amendment to the Code of Federal Regulations, Title 21 Paragraph 3.__, Formal Statements of Policy or Interpretation. As I understand these statements they are intended to reflect the opinions of the Commissioner or declare his position in a given matter. For that purpose they are very valuable instruments. In

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a practical way these statements are highly regarded and may be commonly observed as if they were law. However they are not substantive regulations and are inappropriate vehicles for mandates such as Par. 3.__ Use of polychlorinated biphenyls (PCB's) in the production and storage of animal feed. "(b)(3) Within 30 days following the effective date of this order, the management of establishments producing animal feed shall: (i) Have the heat exchange fluid used in existing equipment or machinery sampled and tested etc. etc. (ii), (iii), and (iv)."

Presuming non-compliance, what law has been violated? What prohibited act has been committed? What charge will be brought? What penalties have been provided?

With but a modest knowledge of the Food, Drug and Cosmetic Act, I fail to find that an authority for such mandates has been granted to the Secretary or his delegate, or that failure to comply is a prohibited act.

The same considerations are applicable to the proposal: Par. 3__ Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials. (b)(1) and (b)(2). These mandates are without authority and non-compliance is not a prohibited act within the language or intent of the Food, Drug and Cosmetic Act.

As to the proposal to add Section 128.4, Equipment and Utensils, I agree that the so-called "Current Good Manufacturing Practice Regulations" provide for the industries a valuable expression of what the Commissioner believes should characterize various commercial operations. I do not believe these statements have the stature of substantive regulations and they are inappropriate as vehicles for the mandates provided in this proposal.

It is my opinion that, phrased as Formal or Informal Statements of Policy or Interpretation the guidance provided by these proposals would

be most valuable to all concerned.

Under the authority granted in Sec. 406, FD&C Act, 21 USC 346, the Commissioner proposes to add a new Part 122 to the Code of Federal Regulations. Of significance to this objection is the proposed Par. 122.10 Tolerances for Polychlorinated biphenyls (PCB's). It may be noted that the proposed tolerances are temporary. The Commissioner's office has advised that these are to be further reduced to the extent practical as the elimination of PCB's from food and food-packaging materials progresses.

The question here is not the benevolence of the Commissioner's intent to eliminate PCB's from foods and food-packaging materials. No one who believes in the virtue of pure food can disagree with such purpose.

To understand what is happening in these proposals and the subtle violence being done to the FD&C Act requires a careful analysis. Without the credentials to interpret law, I may indeed be rushing in where wise men fear to tread. However, I believe that scientific truth supports these arguments and that the issue in essence has been litigated in the case called Lexington Mill and Elevator Co. That was done in a strict judicial and scientific climate whereas today's political and emotional climate tends to prevail over strict adherence to scientific fact.

First there is no question of the authority of the Commissioner to propose tolerances under Sec. 406. The question is whether or not the proposed tolerances meet the criteria intended by law. Once the requirements of public procedure are complete, tolerances under Sec. 406 become regulations having the force and effect of criminal law. Upon a determination

that any one of the tolerances have been violated the Commissioner is required to charge that the offending articles are unsafe, to remove them from commerce, enjoin against further violations and/or prosecute those who commit the prohibited act. Classically the removal from the channels of commerce is accomplished by seizure action charging under Sec. 402(a)(2)(A) that the food is adulterated in that it bears or contains a substance which is unsafe within the meaning of Section 406. Section 406 provides that for any poisonous or deleterious substance which cannot be avoided by good manufacturing practice or is required in the production of the food, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary to protect the public health.

Nowhere do we find in the language or intent of the Food, Drug and Cosmetic Act that the Secretary has the authority to set tolerances more restrictive than those necessary to protect the public health nor to use some other basis for tolerances in these sections of the Act which relate to Sec. 402(a)(1) "adulterated and unsafe". Thus the charge, "adulterated and unsafe" within the meaning of Section 406 must mean what it says. The offending article may not arbitrarily be deemed unsafe because the producer or manufacturer did not meet a tolerance based on what the Commissioner believes can be attained. The determination of "unsafe"is to be arrived at in view of the other ways in which the consumer may be affected by the offending substances or other poisonous or deleterious substances[1], but

1. Sec. 406 . . . . 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.

these provisos do not alter the meaning of the term. This same guidance is restated in Sec. 408[2] and Sec. 409[3]. In brief the contention is that Tolerances under Sec. 406 must cleave between that which must be deemed unsafe and that which must be deemed safe and not between what manufacturers or producers can reasonably achieve and what would be so severe as to cause undue hardship.

Neither does the Commissioner have authority to propose tolerances which are more lenient than those necessary to protect the public health. To do so subjects the consumer to food in the market place which is unsafe, or which in view of the sum of all of the vectors by which the offending substance and its pharmacological counterparts affect man, must be deemed to be unsafe. It follows that tolerances established cannot be temporary with the intent of proposing lower tolerances at an appropriate time. The Commissioner's only choice is to propose tolerances which with the best toxicological advice available condemns that which must be deemed to be unsafe and permits that which must be deemed to be safe. Exception to the rule might be noted in time of food shortage or famine when a higher tolerance is recognized as a justifiable risk. Likewise, tolerances may be raised or lowered with the advent of new information concerning toxicity, mutagenicity, teratogenicity or other health facet, also with

2. Sec. 408 (b) . . . . In establishing any such regulation, the secretary shall give appropriate consideration, among other relevant factors, (1) . . . . (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious.

3. Sec. 409(c)(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors---(a) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive; (b) 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 (c) 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.

changes in per capita ingestion of the concerned substance from all known sources and also as other new facts provide a better scientific basis for decision. To be between the horns of this dilemma may be unpleasant for the Commissioner and his advisors but both producers and consumers of food are entitled to a just decision based on the best scientific advice available.

This objection to the proposed tolerances, Sec. 122.10 is based on the contention that the tolerances do not delineate between that which must be deemed unsafe or safe but that they attempt to identify temporarily the current goals for industry practice. They reflect the Commissioner's opinion as to what food and food-packaging producers can achieve for the present. In other words the proposed tolerances are based on the chemistry of the problem and are not the product of a toxicological determination that a violation must be deemed to be unsafe in the same sense the term is defined in Sec. 406 and further elucidated in Sec. 408 and Sec. 409.

The question arises why should the Commissioner be constrained by considerations of hazard to health in his sincere and praiseworthy effort to reduce the amount of a poison in food to the least amount technologically possible. The emotionally unpalatable answer lies in the fact that in the strict scientific sense there are no poisonous or deleterious substances but only poisonous or deleterious amounts of substances. Below the level at which health hazard begins, a substance is neither poisonous or deleterious. Emotionally it may be impossible to accept the concept that a highly toxic substance or even a moderately toxic substance such as PCB's are not poisons. Scientifically there is no question. In some amount every substance is safe and in another amount every substance is poisonous and deleterious. Nothing is of itself safe and nothing is

of itself poisonous.This observation has been made by the National Academy of Sciences[4,5] and repeatedly by other responsible persons at least since the time of Paracelsus. (ca 1530 A.D.)

To me what is required in the promulgation of a tolerance under Sec. 406 is a toxicological conclusion based on today's knowledge (not including some future undefined concern as to mutagenicity and teratogenicity) that defines the point at which the best scientific advice the Commissioner can command, says the article of food must be deemed unsafe. By public procedure these conclusions are exposed to the best scientific minds in the nation for comment. Out of such deliberations come the levels (tolerances) at which the Commissioner may and must seize and destroy offending articles of food.

There is some apparent support for the Per Se Poison Theory in portions of the text of the Food, Drug and Cosmetic Act. Section 406 begins with a condemnation of "Any poisonous or deleterious substance

4. Chemicals are used in various phases of food production and technology. Those that occur in the food as the result of such use are termed "chemical additives". The regulation, in the interest of public health, of the extent of occurrence of these chemicals in food is based in part on the established toxicologic principle that there is a "safe level" of intake for any chemical. An additional principle, which has not been generally recognized or, in fact, stated, enters into such regulation. This principle permits the ignoring of the presence of known, finite quantities of chemicals in food as though there were none present. There has been some tendency to use the term "zero" to include such finite, though ignorable, amounts. It seems preferable to recognize that these amounts are finite but that they are insignificant or inconsequential insofar as public health is concerned.
Statement by the Food Protection Committee, Food and Nutrition Board, National Academy of Sciences, National Research Council, Food Drug Cosmetic Law Journal, Commerce Clearing House, Inc. Chicago, July 1958 p.477

5. For every compound there is a level of intake below which there is no discernible effect upon health. In toxicologic testing, a level of intake of a compound having no demonstrable effect upon at least two species of animals when fed over a long period is generally referred to as a "no-effect level". Extrapolation from the "no-effect level" in animals has been successful in defining a level of intake which has a negligible probability of injuring any individual in the population. This level is commonly referred to as the "safe level" for use by man.
Ibid p. 478

added to any food . . . . shall be deemed to be unsafe . . ."
This simplistic language, probably expedient politically for the passage of the Act, was repeated in adding to the law, the Pesticide Amendment, Sec. 408, and the Food Additives Amendment, Sec. 409. Other phrases in the FD&C Act seemingly support the Per Se concept unless they are read in the context of the scientific fact that no substance is poisonous or deleterious except in the amount sufficient to enable it to be poisonous or deleterious. In the immediate instance PCB's are not poisonous or deleterious in any amount but only in that amount in which they may be harmful to man under the comprehensive guidelines provided in Sec. 406 and further amplified in Sec. 408 and Sec. 409.

It may be proposed that in the Food, Drug and Cosmetic Act of 1938 the Congress chose to renounce or relinquish the intent of the prior Act and espouse the Per Se Poison concept by law. Certainly the casual reading of Sec. 406 would suggest that. This would then vest in the Commissioner the power to identify an offensive substance as Poisonous or Deleterious, to seize and destroy offending articles of food as "deemed unsafe", to set successively more rigorous tolerances until the affected industry or agriculture had reached the limit of technological capability to exclude it. In a popularity contest managed by skillful promoters in today's highly emotional climate there is no telling how loudly the clamor for this view might become. The problem is that not even the Congress can invalidate what scientific experience shows to be truth nor was it ever their intention to do so.

In addition to what I believe can be logically deduced, two matters compel this difference of opinion with the Food and Drug Administration. First, the charge that food is adulterated and unsafe must result in the

seizure of property and in the instance at hand the destruction thereof by some means that will not contaminate another facet of the environment with PCB's. To quote Chief Justice Warren, "When society acts to deprive one of its members of his life, liberty or property, it takes its most awesome steps . . . . The methods we employ in the enforcement of our criminal law have aptly been called the measures by which the quality of our civilization may be judged."[6] I do not believe that the Congress in the Food, Drug and Cosmetic Act intended to grant to the Commissioner the power to seize a man's property as adulterated and unsafe for violation of a limit that reflected the Commissioner's judgement of what was possible. On the other hand the Commissioner should have little choice but to seize property that contains an amount of some substance which a carefully considered toxicological opinion must regard as unsafe.

Secondly, the concept of a constraint on the Commissioner's authority to limit an offensive substance in food has been considered in the case of US vs Lexington Mill and Elevator Co.[7]

Though there is no case history of litigation directly on the Per Se Poison Theory for the reason that scientific fact does not lend itself to litigation, i.e. whether or not Arsenic is Per Se poisonous or deleterious to man is not a question of law. In the matter cited, the government seized flour under libel charging adulteration with "nitrites or nitrite reacting material, nitrogen peroxide, nitrous acid, nitric acid and other poisonous and deleterious substances which might render the flour injurious to health."[8]

6. Coppedge vs United States 232 US 399
7. Kleinfeld, Vincent A. and Dunn, Charles Wesley, The Federal Food Drug and Cosmetic Act 1949-50, Commerce Clearing House, Chicago pages 51-55
8. Ibid p.51

The trial court (in error) charged the jury as follows: "The fact that poisonous substances are to be found in the bodies of human beings, in the air, in potable water, and in articles of food, such as ham, bacon, fruits, certain vegetables, and other articles, does not justify the adding of the same or other poisonous substances to articles of food such as flour, because the statute condemns the adding of poisonous substances. Therefore the court charges you that the Government need not prove that this flour or foodstuffs made by the use of it would injure the health of any consumer. It is the character--not the quantity--of the added substance, if any, which is to determine this case." [9]

The Circuit Court of Appeals held that the trial court erred in instructing the jury that the addition of a poisonous substance in any amount would adulterate the article for the reason that "the possibility of injury to health due to the added ingredient and in the quantity in which it is added is plainly made an essential element of the prohibition." [10]

Upon a writ of certiorari the Supreme Court upheld the Court of Appeals. Though the use of the words poisonous or deleterious in this opinion have overtones of the Per Se Poison Theory the court recognized clearly the intent of Congress to condemn food containing an added poisonous or deleterious ingredient only when such addition might render the article of food injurious to health. [11]

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9. Ibid p.52

10. Ibid p.52

11. If it can not by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act. Ibid p.54

Whether or not the proposed tolerances (FR March 18, 1972) in fact delineate between that which must be deemed unsafe and that which must be deemed safe is a question for scientists with appropriate credentials. What levels the industries can "live with" now (temporarily) and attain later with diligent effort is irrelevant. If food in the market place is unsafe by virtue of PCB's it must be removed from the channels of commerce. If food in the market place is safe the proposed tolerances should be reconsidered and any unfortunate incidents or accidents corrected by FDA and USDA as heretofore. The Commissioner states that "the current dietary level is not considered an immediate hazard to the public health." By deleting the word immediate, we have a more forthright statement, "the current dietary level of PCB's is not considered an hazard to the public health." In view of the fact that the production and use of PCB's in the U.S. have within the past two years been drastically curtailed and controlled there is little reason to expect that the situation will worsen. Are there more effective ways in which the objective of further reducing the level of PCB's in animal feeds, feed components, and food for human use can be achieved even though the the current dietary levels present no hazard to the public health? The fact that there are ways to accomplish the objective has been aptly put in a recent presentation by Richard J. Ronk before the 15th Annual Educational Conference of the Food and Drug Law Institue and the Food and Drug Administration, "It is recognized that the integrity of the product is the undiluted responsibility of the manufacturer. However the ultimate solution to these problems where contaminants are incorporated and concentrated from the environment will require the concerted effort of consumers, industry, and government".[9]

9. Ronk, Richard J. Chemical Food Contamination and Product Integrity, Food Drug Cosmetic Law Journal, Commerce Commerce Clearing House, Inc. Chicago Vol. 27 No. 2, February 1972, p.96.

subsequent decision in Bristol-Myers Co. v. FTC, 424 F.2d 935 (D.C. Cir. 1970), where it was even suggested that "substantial delay in * * * achieving such disclosure as the statute requires" would authorize the courts to "consider the propriety of granting temporary relief" against further proceedings on a notice of proposed rule making (424 F.2d at 940).[1/]

Moreover, we have not yet received the statement required by Section 102 (2)(C) of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. §4332 (2) (C)) on the environmental impact of the proposed rules, which, according to Associate Commissioner Fine's letter of April 6, 1972, is currently in the drafting stage. The mandate of NEPA is that environmental values be given full consideration by agency officials "at every distinctive and comprehensive stage of the [agency] process beyond the staff's evaluation and recommendation." Calvert Cliffs' Coordinating Committee, Inc. v. AEC, 449 F.2d 1109, 1119 (D.C. Cir. 1971). Compliance with that mandate, as the Court of Appeals recently indicated,

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1/ The rule making in Bristol-Myers was pursuant to Section 4 of the Administrative Procedure Act (5 U.S.C. §553), rather than in a two-stage procedure such as Section 701(e) of the Food, Drug & Cosmetic Act (21 U.S.C. §371). The principle is thus plainly applicable to all aspects of the present rule making proposal and not merely to those subject to Section 701 (e).

It would seem that the PCB problem must be in its final stages. Somewhere between 1929 when PCB's were first produced and Aug. 1970 when sale for open system usages ceased, the exposure of the American consumer to PCB's reached its zenith. Recently there were accidents involving poultry feed quickly controlled by FDA and USDA. Meanwhile the Commissioner has repeatedly assured the public that no hazard to health exists. As a measure of prudence toward eliminating long term low level human exposure the further removal of PCB's from our environment would appear best served by the cooperative efforts of government, business, and industry. There yet remain PCB's which can be physically aggregated and destroyed which otherwise by the nature of their usage may reasonably be expected to be dissipated into the environment to ultimately affect water and food. In addition to a search of the industrial locations as proposed, which may yield PCB's, consideration can be given to suitable destruction of the PCB type self-copying paper. Personal experience leads me to believe that there are still sizeable quantities of this type of copy paper in business firms, public institutions and government which can be identified, collected and destroyed as a wholesome gesture toward the purity of our ecology, water supply, food and animal feed. At 30,000 parts per million even the ordinary handling of this paper must result in some exposure. Only very recently have I encountered PCB type paper as follows: (1) receipt for deposit at a federal credit union, (2) receipt for fare paid for a sight-seeing trip by bus, (3) order pad used by waitress in a restaurant. (4) self copying adding machine tape in a bank (5) hotel statement on check out. Newer forms of self-copying paper are available, nevertheless the PCB type is still in use and can be segregated and collected for controlled incineration as the only practical known means of destroying the PCB's.

Respectfully submitted,

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