The original documents are located in Box 11, folder "Supreme Court Nomination - Opinions of John Paul Stevens on Environmental Questions" of the Richard B. Cheney Files at the Gerald R. Ford Presidential Library.

RBC HAS SEEN

THE WHITE HOUSE

WASHINGTON

November 25, 1975

MEMORANDUM FOR: DICK CHENEY

FROM: PHIL BUCHEN P.

At our meeting on Saturday, the President asked what Judge Stevens' views were on environmental questions. Attached is a memo from Ed Schmults to me in regard to this subject.

Attachment

THE WHITE HOUSE

WASHINGTON

November 24, 1975

MEMORANDUM FOR: PHIL BUCHEN

FROM: ED SCHMULTS

SUBJECT: Opinions of John Paul Stevens on Environmental Questions

Attached are three opinions of Judge Stevens on environmental questions and one opinion on a Motor Vehicle Safety Standard. Brief summaries of the cases are as follows:

Stream Pollution Control Board for the State of Indiana v. U. S. Steel Corp., 512 F. 2d 1036 (7th Cir. 1975). The Indiana Stream Pollution Control Board brought a common law public nuisance action against U. S. Steel to abate pollution of a navigable stream. Appellant, a private citizen, sought to intervene and a motion to do so was denied below. Appellant alleged that his interests in Lake Michigan and the environment of Indiana might be adversely affected by the proceedings and claimed a right to intervene under the Federal Water Pollution Control Act Amendments of 1972. After finding that federal jurisdiction of the State Board's underlying claim could be founded on a federal common law of public nuisance, Stevens held that appellant's motion to intervene was correctly denied. Stevens said that U. S. Steel was in compliance with the federal Act since the effluent standards had not yet become effective. He disagreed with a construction of the Act that would say all effluents are prohibited until limitations thereon are effective.

Stearns Electric Paste Co. v. Environmental Protection Agency, 461 F.2d 293 (7th Cir. 1972).
Under the Federal Insecticide, Fungicide and Rodenticide Act, EPA had determined that Petitioner's rat and roach poison, which had been sold since 1878, was too dangerous for home use except by commercial pest control operators. Under the FIFRA, EPA is authorized to refuse, or to cancel, the registration of any misbranded poison. Stevens said that it was fair to state that the contents of the poisons' labels were largely irrelevant and the real question was whether the FIFRA included a substantive standard of product safety. Evidence was that the product was very effective, but had caused significant mortality and morbidity, largely resulting from suicidal ingestions. Stevens found no statutory support for application of a substantive standard of product safety to misuse of a product. "Without such support, the formulation of substantive standards of product safety by an administrative agency expands the scope of administrative discretion beyond permissible limits." He said that the fact that a legislature may react slowly to obvious dangers cannot justify an agency's policy determinations that are not authorized by statute. The EPA cancellation order was set aside.

U.S. v. Ewig Bros. Co., Inc., 502 F.2d 715 (7th Cir. 1974).
The question was whether DDT and Dieldrin in smoked chubs taken from the Great Lakes are "food additives" within the meaning of the Federal, Food, Drug and Cosmetic Act. If the answer is yes, then presumably all fish in the Great Lakes are "adulterated" within the statutory definition and, therefore, EPA could eliminate all such fish from our food supply. Stevens found that the presence of DDT in fish caused "adulteration" in fish within the meaning of federal law. He found that the government's enforcement guidelines were based on adequate standards of measurement

* This point was made in the opinion to indicate that the question of statutory interpretation had to be approached with much care, although even a cautious interpretation did lead the Court to conclude in favor of the Government's case.

and the government had proved that those guidelines were exceeded repeatedly and, therefore, the federal law had been violated.

H & H Tire Company v. U.S. Department of Transportation, (7th Cir. 1972).

Under the Nation Traffic and Motor Vehicle Safety Act, DOT had prescribed a standard requiring re-treaded tires to meet the same performance specifications as those established for new tires. The Act stated that all standards should be "reasonable, practical and appropriate." Petitioner alleged that the re-tread standard did not satisfy these criteria. The court found no economic analysis or adequate investigation of practicability by DOT and set aside the re-tread standards. Stevens, in a concurring opinion, said that what the government agency had done, in effect, was to tell car owners that they cannot buy re-treaded tires. He said that the agency should identify the costs associated with the standard and determine whether the costs are overridden by reasonably predictable benefits; since he found no such consideration, Stevens agreed that DOT had failed to perform its statutory duty.

STEARNS ELECTRIC PASTE COMPANY, Petitioner,

v.

ENVIRONMENTAL PROTECTION AGENCY, Respondent.

No. 71-1112.

United States Court of Appeals, Seventh Circuit.

May 11, 1972.

Argued Dec. 10, 1971.

Decided May 11, 1972.

Petition by manufacturer of phosphorous paste rodenticide for review of order of the administrator of environmental protection agency which canceled manufacturer's registrations of its product and banned the phosphorous paste from home use. The Court of Appeals, Stevens, Circuit Judge, held that application of standard that product is "misbranded" because when used in accordance with commonly recognized practice it is injurious to living man was beyond the authority Congress had delegated to the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act when applied to phosphorous paste rodenticide from which harm had occurred only by misuse.

Cancellation orders set aside.

1. Agriculture ⇐9

Interpretation by Environmental Protection Agency of Federal Insecticide, Fungicide and Rodenticide Act with respect to labeling of phosphorous paste products was mere announcement of the agency's position which did not have legal effect of regulation. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

2. Health and Environment ⇐25.5

Although not required by law to do so, Environmental Protection Agency acted properly in soliciting comments on its proposed policy statement before issuing interpretation pertaining to labeling of phosphorous paste products and in giving industrywide notice of its proposed position. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2 et seq., 4, 7 U.S.C.A. §§ 135 et seq., 135b.

3. Poisons ⇐2

Availability to registered poison manufacturer of an evidentiary hearing before registration cancellation order is effective, together with safeguard of appellate review, adequately protects a registrant's procedural rights in proceeding under Federal Insecticide, Fungicide, and Rodenticide Act to cancel registration. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

4. Poisons ⇐2

Under the Federal Insecticide, Fungicide, and Rodenticide Act, the burden of proof in a registration cancellation proceeding that the registration complied with the statute was on the registrant. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

5. Poisons ⇐2

In order to be entitled to registration under the Federal Insecticide, Fungicide, and Rodenticide Act, the economic poison product must be at least as effective as the registrant claims it to be. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

6. Poisons ⇐2

Evidence established that registrant's phosphorous paste rodenticide met standard for registration under Federal Insecticide, Fungicide, and Rodenticide Act that the product be at least as effective as the registrant claimed it to be. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

7. Poisons ⇐3

Evidence of long history of use of registrant's phosphorous paste rodenti-

cide, involving broad distribution and numerous repeat orders, coupled with absence of claims or evidence that injury had actually resulted from use of product in compliance with directions, was sufficient to make prima facie showing that the label accompanying the product contained directions for use and a warning or caution statement which, if complied with, was adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals. Federal Insecticide, Fungicide, and Rodenticide Act, § 2(z) (2), (2) (c, d, g), 7 U.S.C.A. § 135(z) (2), (2) (c, d, g); Federal Food, Drug, and Cosmetic Act, §§ 402, 403, 501, 502, 21 U.S.C.A. §§ 342, 343, 351, 352.

8. Poisons ⇐3

Registrant made prima facie case that its phosphorous paste product, when used as roach and water bug killer, was not misbranded when used as directed or in accordance with commonly recognized practice. Federal Insecticide, Fungicide, and Rodenticide Act, § 2(z) (2), (2) (c, d, g), 7 U.S.C.A. § 135(z) (2), (2) (c, d, g); Federal Food, Drug, and Cosmetic Act, §§ 402, 403, 501, 502, 21 U.S.C.A. §§ 342, 343, 351, 352.

9. Health and Environment ⇐25.5

The standard to measure the net injury resulting from use of economic poison in compliance with directions depends on the intricate balance between the benefit and dangers to public health and welfare resulting from its use and the administrator of the Environmental Protection Agency must determine and weigh the nature and magnitude of foreseeable hazards associated with use of particular product against the nature and the benefit conferred by the use of the product. Federal Insecticide, Fungicide, and Rodenticide Act, § 2(z) (2), (2) (c, d, g), 7 U.S.C.A. § 135(z) (2), (2) (c, d, g); Federal Food, Drug, and Cosmetic Act, §§ 402, 403, 501, 502, 21 U.S.C.A. §§ 342, 343, 351, 352.

10. Poisons ⇐3

The "intricate balance" test of misbranding of economic poison was not appropriate in proceeding for cancellation of registration of phosphorous paste rodenticide, a product which was harmful only when not used in compliance with directions and which was harmful to specific individuals rather than to the total environment. Federal Insecticide, Fungicide, and Rodenticide Act, § 2(z) (2), (2) (c, d, g), 7 U.S.C.A. § 135(z) (2), (2) (c, d, g); Federal Food, Drug, and Cosmetic Act, §§ 402, 403, 501, 502, 21 U.S.C.A. §§ 342, 343, 351, 352.

11. Poisons ⇐2

In any balancing test used to measure the acceptability of public sale of poisonous substances, it is imperative that the emotional impact of dramatic but unfortunate tragedies not be permitted to weigh too heavily on the scales. Federal Insecticide, Fungicide, and Rodenticide Act, § 2(z) (2), (2) (c, d, g), 7 U.S.C.A. § 135(z) (2), (2) (c, d, g); Federal Food, Drug, and Cosmetic Act, §§ 402, 403, 501, 502, 21 U.S.C.A. §§ 342, 343, 351, 352.

12. Poisons ⇐3

The danger of misuse of poisonous product is a proper subject of regulatory concern which must be related to the form of the labels. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

13. Poisons ⇐3

Standard that a product is misbranded whenever its label fails to prevent injury to man is too strict and is not proper in proceeding to cancel registration of poisonous substance under the Federal Insecticide, Fungicide, and Rodenticide Act. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

14. Poisons ⇐2

Fact that phosphorous paste rodenticide was subject to misuse was not sufficient reason for administrator of Environmental Protection Agency to

cancel its registration under the Federal Insecticide, Fungicide, and Rodenticide Act. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

15. Poisons ⇐3

Isolated incident of misuse causing harm, or even death, to particular individual is not within contemplation of the phrase "injury to man" within statute providing that any economic poison shall be considered misbranded if the label does not contain warning or caution statement adequate to prevent injury to living man. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

See publication Words and Phrases for other judicial constructions and definitions.

16. Poisons ⇐3

A statute, such as the Federal Insecticide, Fungicide, and Rodenticide Act, which is primarily a regulation of labels necessarily assumes that the general public does heed warning; a fair respect for the statute requires rejection of test of misbranding predicated on total illiteracy or universal disregard of instructions. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

17. Poisons ⇐3

The adequacy of a label on a poisonous product will be affected by the nature of the message to be conveyed and the ability of the reader to comprehend its meaning and if product is not safe unless intricate or esoteric instructions printed in small type are followed with precision, use by laymen, even if reasonably careful, would create obvious risk of injury to man. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2) 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

18. Poisons ⇐3

Disregard by consumer of conspicuous warning such as "POISON—KEEP AWAY FROM CHILDREN," would constitute gross negligence. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

19. Poisons ⇐3

The Environmental Protection Agency has adequate power under the Federal Insecticide, Fungicide, and Rodenticide Act to require the elimination of possible ambiguity in labeling of dangerous product by requiring appropriate revisions and more emphatic warnings. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

20. Health and Environment ⇐25.5
Poisons ⇐3

Application of standard that product is "misbranded" because when used in accordance with commonly recognized practice it is injurious to living man was beyond the authority Congress had delegated to the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act when applied to phosphorous paste rodenticide from which harm only occurred by misuse. Federal Insecticide, Fungicide, and Rodenticide Act, §§ 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

21. Poisons ⇐3

The phrase "commonly recognized practice" as used within labeling provisions of Federal Insecticide, Fungicide and Rodenticide Act relate to common practices which are "recognized" in the sense that they are approved by widespread custom or practice. Federal Insecticide, Fungicide, and Rodenticide Act, § 2(z) (2) (d, g), 7 U.S.C.A. § 135(z) (2) (d, g).

See publication Words and Phrases for other judicial constructions and definitions.

22. Poisons ⇐3

Provision of Federal Insecticide, Fungicide, and Rodenticide Act that any economic poison shall be considered misbranded if, when used as directed or in accordance with commonly recognized practice, it shall be injurious to living man, does not apply to rodenticides.

Federal Insecticide, Fungicide, and Rodenticide Act, § 2(z) (2) (d, g), 7 U.S.C.A. § 135z(2) (d, g).

23. Poisons ⇐3

Manufacturer of phosphorous paste rodenticide made prima facie case in registration cancellation proceeding that its product was not mislabeled. Federal Insecticide, Fungicide, and Rodenticide Act, § 2(z) (2), 4(c), 7 U.S.C.A. §§ 135(z) (2), 135b(c).

Esther O. Kegan, Michael G. Berkman, of Kegan, Kegan & Berkman, Chicago, Ill., for petitioner.

Charles Blaine Fielding, Office of the General Counsel, U. S. Environmental Protection Agency, Alan S. Rosenthal, Robert E. Kopp, Department of Justice, L. Patrick Gray, III, Asst. Atty. Gen., Michael C. Farrar, Asst. Gen. Counsel, Washington, D. C., for respondent.

Before KILEY, FAIRCHILD and STEVENS, Circuit Judges.

STEVENS, Circuit Judge.

The labeling of economic poisons is regulated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[1] All such poisons distributed in interstate commerce must be registered with the Administrator of the Environmental Protection Agency.[2] The Administrator is authorized by FIFRA to refuse, or to cancel, the registration of any poison that is misbranded.[3]

Since 1878 petitioner has been selling phosphorous paste for home use as a rat and roach poison. Its English and Spanish language labels, as modified from time to time, have been registered since shortly after the registration requirement became effective in 1947. On January 4, 1971, the Administrator cancelled these registrations on the ground that phosphorous paste is too poisonous for use in the home except by commercial pest control operators.

The cancellations were precipitated by a review of petitioner's labels, but it is fair to state that the contents of the labels were irrelevant to the determination that the product was too dangerous to be permitted in the home. The evidence plainly showed that phosphorous paste is extremely toxic, that it possesses "great potential for harm," as the Hearing Examiner found, and that both adults and children have been killed or hospitalized by misuse of the product. On the other hand, there is no finding, and little or no evidence, of mortality or morbidity resulting from the use of the product in compliance with the directions on the

1. 61 Stat. 163, 7 U.S.C. §§ 135–135k.

2. 7 U.S.C. § 135b. The administration of FIFRA, which was initially entrusted to the Secretary of Agriculture, is now committed to the Administrator of the Environmental Protection Agency by virtue of Reorganization Plan No. 3 of 1970, 35 Fed.Reg. 15623, 84 Stat. 2086, 5 U.S.C. App., p. 609 (1970 ed.) (effective December 2, 1970).

3. 7 U.S.C. § 135b(c). The statute authorizes the Administrator to refuse registration if it does not appear "that the article is such as to warrant the proposed claims for it or if the article and its labeling and other material required to be submitted do not comply with the [Act]. . . ."

7 U.S.C. § 135(z) (2) provides that any economic poison shall be considered misbranded:

> "(c) if the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public;
>
> (d) if the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals;
>
> * * * * *
>
> (g) if in the case of an insecticide, nematocide, fungicide, or herbicide when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds, to which it is applied, or to the person applying such economic poison;"

The Administrator may suspend the registration during a cancellation proceeding if he finds that the insecticide presents an "imminent hazard" to the public. 7 U.S.C. § 135b(c).

label.[4] The theory of the cancellation order was succinctly explained by the Government's principal witness who testified "that the general public is incapable of handling these things and following directions." [5]

Petitioner's challenge to the cancellations raises both procedural and substantive questions of first impression.[6] At the heart of the controversy is the question whether FIFRA includes a "substantive standard of product safety [7]," and if so, what that standard is. Because of the novelty and importance of the issues, we shall state the facts in some detail, then review the statute, and finally test the findings against it.

I.

Stearns Electric Brand Paste is an inexpensive and effective killer of rodents, roaches, water bugs and similar pests. The active ingredient in Stearns Paste is white phosphorus, a highly toxic substance, for which—as is true of most poisons—there is no known antidote.[8] Phosphorous paste is the only kind of poison which is sold as both a rodenticide and roach killer. It is also the only product sold by petitioner. If an adult swallows over half a tube, "the odds are" that the ingestion will be fatal. Ingestion of much smaller quantities may prove fatal to children. The record plainly supports the finding that the product possesses "great potential for harm." (A. 269, Judicial Officer's decision.)

Petitioner markets its product through distributors and by direct mail. About 300,000 tubes are sold annually at a retail price of about 69 cents per tube. Since each tube contains enough paste

4. The Judicial Officer's conclusions, adopting the recommendations of the Hearing Examiner, contained the following somewhat ambiguous statement:

"The record herein and the record before the then Director, Pesticides Regulation Division, prior to the promulgation of Interpretation 26, demonstrate numerous instances of morbidity or injury especially to children and fatalities resulting from the accidental ingestion of phosphorus paste insecticide and rodenticide when utilized as directed and when misused based on what appears to be the best data available although such data is limited in scope and is often lacking in detailed information." A.271.

However, as noted in the text, there is no specific finding of injury from Stearns Paste when used as directed. Certainly, it is impossible from the evidence or the findings to appraise the extent of such injury.

5. "Q So I want to get it perfectly clear that as far as Dade County, which has among the better recordkeeping offices in the country, there is no evidence of any death in the proper use of Stearns Paste in accordance with the label direction?

"A That's correct. I have no argument with that, and my only comment—I am not saying it to be argumentative—but just amplifying my philosophy on the use of poisons by the general public, my only comment is that the general public is incapable of handling these things and following directions.

"I mean, we are dealing here with a class of people for the most part who cannot read or write. We now have a major segment of our society down there who are Spanish-speaking, and read Spanish. I don't know if the labels—in fact, I have seen no evidence of Spanish labels on many of our pesticides and hazardous products that are made available to the public.

"It is my considered opinion that the public has the potential, and it is a real potential, of abusing and misusing a product, and therefore, we have to consider when we release products to the public this real potential.

"It is always there, and this is one of the major factors that we have to consider in reference to certifying anything that is made available to the public." Tr. 316-317. Excerpt from testimony of Dr. Joseph Davis.

6. Respondent has advised us that the order under review in this litigation was the first final cancellation order issued by the Administrator after completion of the administrative procedures set forth in the statute.

7. See Enviromental Defense Fund, Inc. v. Hardin, 138 U.S.App.D.C. 391, 428 F.2d 1093, 1095, n. 2 (1970).

8. See testimony of Dr. Davis: "There are very few poisons for which there is a real antidote." Tr. 288.

for about 50 baits, it is estimated that 72 million baits of Stearns Paste have been used in the past five years. The Company receives about 1500 letters a year from customers who have moved and cannot find a local source of the product; many of these letters state that Stearns Paste is the best rat or roach killer the writer has used. The effectiveness of the product is not disputed; indeed, the question is whether it is too poisonous to be permitted in homes.

The tube is plainly labeled in black and red print as "POISON," with the skull and crossbones symbol and instructions for use printed in black and red letters. The tube is sold in a paper carton, which also contains an explanatory insert. The insert and carton, like the tube, prominently display the poison warnings.[9]

The record indicates that other products which will kill rats, and other products which will kill roaches, are available. Petitioner's evidence tended to show that the alternatives were less effective and more expensive. The evidence also indicated that rats and roaches pose a significant health problem, particularly in low income areas. Apparently the services of a commercial pest control operator cost at least $35 per visit. The findings do not specifically consider the magnitude of the danger from rats or roaches. Although the findings recognize the availability of various other rodenticides and pesticides, the record contains no square finding that any other product is *as effective* as phosphorous paste,[10] or, as-

9. The directions on the tube and carton warn the reader (in red ink) not to "leave Paste in reach of irresponsible persons, children, pets, or domestic animals. Keep Paste away from foodstuffs. Do not apply heat. Wrap used tube well in paper and discard in trash can." Under the label "ANTIDOTE," instructions on how to induce vomiting are followed by advice to "CALL A PHYSICIAN IMMEDIATELY." The instructions for use then follow.
To kill rats and mice, the user is told to "apply Stearns' Electric Brand Paste on bread, cheese, or other food they will eat, leaving it in places where rats run and feed and out of reach of children, pets, or domestic animals. Tamper-proof bait boxes or other suitable protective covers are recommended. Repeat every night until rodents have disappeared."
To kill cockroaches, water bugs and croton bugs, the instructions are to apply the paste "on pieces of paper and place in and about sinks, water pipes, stationary wash basins, etc. In morning carefully burn these pieces of paper and dead bugs, or wrap well in paper and discard in trash can. Repeat every night until rid of these pests."

10. The government argues (Br. p. 16) that "[t]he testimony of several witnesses also bears out [the Judicial Officer's] findings concerning the ready availability of a number of alternative, safer, and effective products and, therefore, establishes the absence of any significant benefit from the use of phosphorus paste [transcript cites]."
The cited references are hardly persuasive. Two experts in toxicology and two physicians who are experts in pathology testified. They spoke on the basis of "impressions" of community usage or "information from my staff." No details whatever were given as to the comparative effectiveness of the alternatives in rodent and roach control in the lower socio-economic areas or of comparative cost or difficulty of administration. Dr. Harris, a chemist, testified other products were available, but he gave no specific information on their effectiveness or availability (Tr. 91–94). Mr. Alford testified only that his staff had assured him other products were available. He named them, indicated proceedings were already under way to ban home use of some, and gave no information on comparative effectiveness and economic availability (Tr. 202–204). Dr. Davis, a pathologist, testified as to his "impression" of community usage and about what a commercial pest control operator told a Miami ordinance-drafting committee. He indicated Warfarin was an alternative but did not discuss its comparative effectiveness (other information in the record indicates that the effectiveness of this product depends on the cumulative effect of several ingestions, whereas one ingestion of Stearns' product would kill the rodent). Dr. Davis testified that he used Baygon insecticide in his home and that it was effective. He also said the government had hired commercial pest con-

that cost is relevant, that any product performing the same function is *equally* available.[11]

As a result of an interagency agreement negotiated in 1964,[12] the Department of Agriculture began to refer economic poison labels to the Food and Drug Administration for toxicological review. In making such review, the FDA applied a general policy that a product that can produce serious injury or death in a small child from an average swallow of about 4½ to 5 cubic centimeters should not be used around the home particularly if there are safer equally effective alternate materials." [13]

On March 8, 1968, in response to a request from Agriculture for a comment on a proposed label revision, FDA objected to the reregistration of petitioner's product pursuant to its general policy against the home use of products that can produce serious injury or death in a small child from an average swallow. Petitioner was then advised by respondent [14] that it would reevaluate its registration policy with respect to products containing phosphorus paste for use in the home."

On October 7, 1968, respondent issued a notice of proposed interpretation "with respect to labeling of phosphorus paste products," and invited comments thereon.[15] The interpretation stated that home use would be unacceptable, but use by government agencies and professional pest control operators would be permitted. Petitioner filed written comments and suggestions which were duly considered and rejected, and on March 19, 1969, Interpretation No. 26 was issued effective 60 days after publication in the Federal Register.[16]

On May 23, 1969, respondent issued notices of cancellation of both of petitioner's registrations.[17] Petitioner filed timely objections and on October 6 and 7, 1970, an evidentiary hearing was held. The Hearing Examiner ruled that the burden of proof was on petitioner, who thereafter presented one witness and 21 exhibits. Respondent's case included the testimony of 8 witnesses and 9 exhibits. After considering the record and argu-

fied operators to use it in Model Cities program areas, but admitted no expert knowledge of the effective use of alternative products in areas not receiving this government aid (Tr. 348, 364–365, 387–389, 394–396). Dr. Fisher, a pathologist, testified "more from personal experience than as an expert" that Warfarin was a safer rodenticide. He too had no information as to its comparative effectiveness (Tr. 433–436). Thus, there was no direct evidence from any expert in pest control as to the comparative effectiveness and availability of alternatives to Stearns' product.

11. A rodenticide which is effective but so highly priced that it is unlikely to be economically available to the people who need it most would not be a practical alternative to registrant's product. Yet, the Assistant Director of the Pesticide Regulation Division of the Department of Agriculture testified that "we don't consider economics in determining whether or not registration is warranted." (Tr. 258).

12. Memorandum of agreement between the Secretaries of Agriculture, Interior and Health, Education and Welfare, 29 Fed. Reg. 5808.

13. Judicial Officer's Finding No. 5, A.258. In February of 1966, petitioner was advised that it would be necessary to make certain changes in its directions for use in view "of the increased emphasis on safe practices in the home environment." Various changes, such as reducing the amount of phosphorus in the paste and the use of scraps of paper instead of bits of food as bait, were thereafter discussed in protracted correspondence between the parties.

14. We use the term "respondent" to refer to representatives of the Department of Agriculture prior to December 2, 1970, and to the Environmental Protection Agency thereafter.

15. 33 Fed.Reg. 15214 (Oct. 11, 1968).

16. 34 Fed.Reg. 5537 (March 22, 1969).

17. "Notices of cancellation were sent to all registrants of the type of product involved herein, numbering 12 or 14 registrants, including Stearns Electric Paste Company, and covering 19 or 20 products. Only one objection to cancellation in addition to Stearns' was filed which objection was subsequently withdrawn." A. 261.

ments of counsel, the Hearing Examiner filed a recommended decision including proposed findings of fact and conclusions. His recommendations were adopted by a judicial officer of the Department of Agriculture, who entered the order of cancellation on January 4, 1971. We stayed the operation of the order pending review in this court.

Respondent's evidence consisted primarily of expert opinion as to the toxicity of phosphorous paste and such data as was available concerning the harm which it has actually caused humans. The statistical evidence included data from the National Clearinghouse for Poison Control Centers [18] and reports from state agencies.

The witness from the National Clearinghouse estimated that there are approximately one million ingestions of harmful substances each year, of which only about 115,000 are reported to a poison control center. The reported ingestions include a wide variety of substances, such as aspirin, kerosene, detergents, and other household products, as well as economic poisons. When measured strictly by the number of reported fatalities, aspirin is the most lethal substance used in the home environment.[19] The National Clearinghouse records placed in evidence in Government Exhibit IV cover the period from January 7, 1962, through August, 1968. Those records describe 207 ingestions of phosphorous paste products, of which 147 were accidental, 51 were suicidal, and 9 were not classified as either accidental or suicidal. A total of 15 deaths resulted, 9 in the suicidal category, 5 in the accidental, and 1 that was unclassified. Forty of the accidental ingestions, 38 of which involved children, required hospitalization. The 5 accidental deaths all involved children.[20]

Stearns Paste accounted for a substantial portion of the total during the 6½ year period. Of the 5 accidental deaths, 3 were attributed to Stearns Paste; of the 51 suicidal ingestions, 20 were Stearns; of the total 207 ingestions, 86 were Stearns.[21]

Since only about 10% of all ingestions of harmful substances are reported to a poison control center, it is reasonable to infer that there may have been a significantly larger number of ingestions of phosphorous paste than is revealed by the record. Since there is presumably a greater likelihood that a poisoning which resulted in death or hospitalization would be reported (at least if correctly diagnosed), it is not clear whether the same inference may be drawn with respect to unreported fatalities. The National Clearinghouse records do establish, however, that at least three children were killed by petitioner's product in the 1962–68 period. Data collected from state agencies for the years 1952 through 1968 indicate that phosphorous paste was responsible for 40 deaths.[22]

18. The formal title of the clearinghouse is "Poison Control Division, Office of Product Safety, Food and Drug Administration."

19. Petitioner's Exhibit 9 is the tabulation of poison reports for 1968 and 1969. In 1968 there were 15,523 cases involving ingestion of aspirin by children under 5 years of age, and over 2,500 cases involving persons over 5 years of age. There were 11 fatalities from aspirin ingestions in 1968. In 1969 there were 14,494 ingestions of aspirin by children under 5 and about 3,000 cases involving older persons. There were 15 aspirin fatalities in 1969. The aspirin fatalities far exceeded those for any other single item. Other figures for 1968 and 1969, respectively, were: Medicine combinations, 32, 27; barbiturate sedatives, 15, 17; psychopharmacologic agents, 11, 16; insecticides of all types, 11, 14.

20. A. 262, Judicial Officer's decision.

21. Id. at 262–263.

22. The record includes responses by 42 state agencies to an inquiry from respondent for information about accidents or incidents involving phosphorous paste products for the years 1952 through 1968. In 13 states there were no reported cases; in 15 states no records of mortality or morbidity from phosphorous paste ingestions were maintained; one state had not completed the search of its records. The

The evidence describing how most of the ingestions actually occurred is sparse. However, the Medical Examiner of Dade County, Florida, and the State Medical Examiner for Maryland have kept better records than most agencies; they provided the examples which respondent stressed in its presentation to the Hearing Examiner.

Dr. Davis, from Dade County, expressed the firm opinion that phosphorous paste is too toxic to be permitted in the home. He was a sponsor of an ordinance in the City of Miami which outlawed the use of the product in that jurisdiction.[23] His data reflects 13 deaths in Dade County in the years 1956 through 1968, of which 10 were probably suicides. The three accidents all involved children. In 1956 a 10-year old boy apparently ingested some paste applied in an apartment building by a professional exterminator; in 1958 a young child found a poison bait in a neighbor's garbage container and swallowed it; in 1960 a 3-year old apparently obtained access to a tube of paste in a home and swallowed part of its contents.

The Maryland records describe 22 deaths in the years 1950 through 1966, of which 15 were suicides, 5 were accidental ingestions by adults (apparently intoxicated), and 2 by children. In 1954 a 4-year old girl found an open can of paste which had apparently been left in an apartment by a former tenant; in 1961, 3 children shared some baits found in or near a garbage can in a neighbor's yard separated from the children's own yard by a four-foot wire fence. One died and two were hospitalized. The Maryland doctor was not asked to produce records indicating the relative importance of phosphorous paste as a cause of death in the home environment, but commented that aspirin is the most common cause of poisoning in children. He estimated that aspirin or other medicinal poisonings killed 2 or 3 children each year in Maryland, which he characterized as a "low incidence."

The record discloses that at least some of the deaths caused by phosphorous paste products followed application by commercial pest control operators; it does not disclose how many children were killed by rats or roaches, or how many were saved from harm by the use of petitioner's product.

After finding that petitioner's product had actually caused significant mortality and morbidity, and that it presented a great potential for harm, the Judicial Officer concluded, in conformity with the Hearing Examiner's recommendations: (1) that petitioner had the burden of proving that the registrations should not be cancelled; (2) that the use of phosphorous paste insecticides and rodenticides in and around the home could not be rendered safe by any label;[24] (3) that petitioner's warning statement, even if complied with, is inadequate to prevent injury to living man;[25] and (4) that the product is "misbranded" because when used "in accordance with commonly recognized practice" it is "injurious to living man";[26] and (5) that he had taken in consideration the fact that effective and less toxic insecticides and rodenticides are available on the market.

Petitioner contends (1) that there were procedural defects in the administrative proceedings; and (2) that Stearns Paste was not "misbranded" within the meaning of the statute. Before discussing these contentions, we shall review the history of FIFRA.

13 remaining states reported a total of 72 accidental ingestions of which 40 were fatal. Many of the ingestions involved children. Id. at 263–264.

23. The text of the Miami ordinance is not in the record.

24. In violation of 7 U.S.C. § 135(z) (2) (c).

25. In violation of 7 U.S.C. § 135(z) (2) (d).

26. In violation of 7 U.S.C. § 135(z) (2) (g).

II.

The Insecticide Act of 1910 prohibited the interstate sale of any insecticide or fungicide which was adulterated or misbranded within the meaning of the statute. 36 Stat. 331. The text of the Act makes it plain that Congress was primarily concerned with the effectiveness of such products and protecting purchasers from deceptive labeling. The Act contained criminal sanctions and provisions for seizure of misbranded or adulterated items, but neither a registration requirement nor a safety oriented labeling requirement.

FIFRA, which repealed the 1910 statute, was enacted in 1947. Like its predecessor, its text indicates a primary interest in protecting consumers from the purchase of ineffective products. However, the coverage of the statute was substantially broadened,[27] a purpose to protect the public from the hazards associated with the use of economic poisons was implemented,[28] and, for the first time, all economic poisons were required to be registered with the Secretary of Agriculture. The registration requirement was included as an aid to enforcement.[29] If the Secretary disap-

27. "This bill embraces, in addition to insecticides and fungicides, rodenticides, herbicides, devices and preparations intended to control other forms of pests which are not subject to the present Insecticide Act of 1910. Rodenticides are being marketed in large quantities and many of them are weak and ineffective and have tended to imperil various rodent-control programs. The importance of rodenticides can readily be appreciated when it is realized that the estimated damage by rats alone has amounted to some $200,000,000 annually." H.Rep. 313 (80th Cong., 1st Sess.), 1947 U.S. Code Cong.Serv. pp. 1200, 1201.

28. "Other important improvements and changes over the present law which would be provided by this bill are as follows:

(1) A provision requiring the registration of economic poisons prior to their sale or introduction into interstate or foreign commerce.

(2) The inclusion of provisions for protection of the public against poisoning by requiring prominently displayed poison warnings on the labels of highly toxic economic poisons.

(3) A provision requiring the coloring or discoloring of dangerous white powdered economic poisons to prevent their being mistaken for flour, sugar, salt, baking powder or other similar articles commonly used in the preparation of foodstuffs.

(4) A requirement that warning or caution statements be contained on the label of the economic poison to prevent injury to living man, other vertebrate animals, vegetation, and useful invertebrate animals.

(5) A provision requiring instructions for use to provide adequate protection for the public.

(6) A provision declaring economic poisons to be misbranded if they are injurious to man, vertebrate animals, or vegetation, except weeds, when properly used.

(7) A provision requiring information to be furnished with respect to the delivery, movement, or holding of economic poisons and devices." Ibid.

29. "One of the principal provisions of the bill is the one providing for the registration of economic poisons prior to their being marketed. It is believed that this provision will provide additional protection for the public, assist manufacturers in complying with the provisions of the bill, and at the same time hold administrative costs to a minimum. Under the existing law, the Administrator has no means of ascertaining or knowing what economic poisons are being marketed, except by having a force of inspectors circulating through the country picking up samples here and there, wherever they may be found. Frequently, serious damage is suffered by agricultural producers and other users of economic poisons through the use of misbranded or adulterated economic poisons before the enforcement officials have any knowledge of the existence of such articles, or of their being offered to the public. Under this bill, any economic poison subject to the provisions thereof will be brought to the attention of the enforcement officials who will have an opportunity to become familiar with the formula, label, and claims made with respect to any such economic poison before it is offered to the public. It should be possible, therefore, in a great majority of instances, to prevent false and misleading claims, and to prevent worthless articles from being marketed, and to provide a means of obtain-

proved of the applicant's proposed labeling, the applicant nevertheless had an absolute right to have his product registered under protest. Thereafter, unless the Secretary could prove in a judicial proceeding that the product was either misbranded or adulterated, he had no authority to exclude it from commerce.[30]

In 1964 the statute was amended to give the Secretary the power to refuse to register a new product, or to cancel an existing registration, if he found that the product was either adulterated or misbranded. The House Report on the 1964 changes and what little floor discussion there was indicate quite clearly that the only major change[31] contemplated was elimination of the registration under protest procedure. The change was made for two basic reasons: (1) to settle the question of compliance with the act before the economic poison could be marketed and (2) to place the burden of proof of safety and effectiveness on the applicant for registration.[32] The concern remained with efficacy and safety "when used as directed."[33] No

ing speedy remedial action if any such articles are marketed. Thus, a great measure of protection can be accorded directly through the prevention of injury, rather than having to resort solely to the imposition of sanctions for violations after damage or injury has been done. Registration will also afford manufacturers an opportunity to eliminate many objectionable features from their labels prior to placing an economic poison on the market." Id. at pp. 1201–1202.

30. There is little legislative history on the 1947 Act. The Senate Report merely reprinted the short House Report (6 pages in U.S.Code Cong.Serv.) and the floor consideration in both houses was perfunctory. The legislative history thus sheds no more light on the meaning of the crucial sections, 7 U.S.C. § 135(z) (2) (c), (d) and (g), than the words of the statute itself. There were some changes made in the Act in 1959, but those changes are not relevant for our purposes.

31. Only one other change of any significance was made. The 1947 Act prohibited any reference on the label to registration under the Act. The 1964 amendments permitted a registrant to put his registration number on the label and required that it be on the label if the Secretary so directed.

32. The House Report pointed out that the protest registration procedure in effect prior to the 1964 amendment placed the burden of proof on the Government and that the bill was intended to "correct this situation." The Report stated, in part:

"The principal effect of registration under protest is to shift the burden of proof from the registrant to the Government. If the product is not registered, the penalty or seizure provisions can be applied on that ground. If it is registered under protest, the Government has the burden of proving that the product does not comply with the act.

Thus, at present, the Secretary can be required to register a product even though he is convinced that it is ineffective and dangerous to human life. He can proceed against it in such case only after it has moved in interstate commerce, and he then has the burden of proving that it violates the law. The bill would correct this situation and afford greater protection to the public by repealing the authority for registration under protest. In its place the bill provides that applicants dissatisfied with the Secretary's action in refusing or canceling registration may have recourse to advisory committee proceedings, public hearings, and eventually judicial review. . . ." H. Rep. 1125 (88th Cong.2d Sess.), 1964 U.S.Code Cong. & Admin.News, pp. 2166, 2167.

33. "According to the Director of the Pesticides Regulation Division of the Department of Agriculture, the 1947 act—known as the Federal Insecticide, Fungicide, and Rodenticide Act—is 'basically a labeling law which protects the public by requiring that the label be adequate to protect the public, *when followed.*' The key protective feature of the law—as pointed out frequently by Department of Agriculture officials over the years—was that all pesticides were required to be registered with the Secretary of Agriculture before they could be sold in interstate commerce. Registration, we have been told, meant that the product was effective and safe *when used as directed.*

* * * * *

"In addition, the legislation requires that every pesticide formulation carry its official registration number on the label. In this way the public will be able to tell at a glance that the product on the shelf has satisfied the requirements of

changes were made in the language of 7 U.S.C. § 135(z) (2) (c), (d) and (g). the provisions with which we are primarily concerned.

III.

As a matter of procedure, petitioner contends that Interpretation 26 is invalid because it was promulgated without a prior public hearing, and that it was error to require a registrant to assume the burden of proving that the proposed cancellations were improper.[34]

[1–3] We agree with respondent's characterization of Interpretation 26 as a mere announcement of the agency's position which did not have the legal effect of a regulation. It is true, as petitioner argues, that the policy expressed in the Interpretation led to the issuance of the cancellation notices, but the Interpretation was not self-executing. Although not required by the Administrative Procedure Act,[35] we think the agency acted properly in soliciting comments on its proposed policy statement before issuing Interpretation 26, and that it was appropriate to give an industrywide notice of its proposed position even though the Interpretation had no immediate legal effect.[36] We are satisfied that the availability of an evidentiary hearing before a cancellation order is effective, together with the safeguard of appellate review, adequately protects a registrant's procedural rights.

[4] We also reject petitioner's contention that respondent, as the proponent of the cancellation order, should have assumed the burden of proof. The 1964 amendment to FIFRA was clearly and specifically intended to shift the burden of proof from the Secretary (now the Administrator) to the registrant.[37] It is true that most of the

Federal law as to its *effectiveness and safety when used according to the directions on the label.*" 109 Cong.Rec. 20080 (1963) (remarks of Sen. Ribicoff on 1964 changes to FIFRA) (emphasis added).

"Provision is also made that registration of any economic poison may be refused if, in the opinion of the Director, directions, or warnings cannot be written which would *when followed* prevent injury to the general public." 109 Cong. Rec. 16446 (1963) (preface to revision of FIFRA regulations inserted by Sen. Ribicoff into the Congressional Record) (emphasis added).

34. Rule 364.28 entitled "Order of Proceeding and Burden of Proof" provides:

"At the hearing, the person whose objections raised the issues to be determined shall be, within the meaning of 5 U.S.C. 556(d) (formerly 5 U.S.C. 1006(c)), the proponent of the order sought, and accordingly shall proceed first at the hearing and have the burden of proof."

35. 5 U.S.C. § 553(b) provides:

"Except when notice or hearing is required by statute, this subsection does not apply—

"(A) to interpretive rules, general statements of policy, . . . ;"

Furthermore, even if 5 U.S.C. § 553 did apply, § 553(c) does not require a hearing but only "an opportunity to participate . . . through submission of written data, views, or arguments." That opportunity was afforded registrant here. We note that the section authorizes, but does not require, an opportunity for oral presentation.

36. Respondent concedes that it could not, at the cancellation hearing, merely rely on Interpretation 26 and that petitioner was entitled to a hearing de novo.

37. See quotation from committee report, *supra*, note 32. See also 110 Cong.Rec. 2948–2949 (remarks by Rep. Sullivan):

"This bill places the burden of proof on industry, to establish that a pesticide can safely be marketed before a certificate of registration can be issued."

Other comments which the congresswoman made earlier and inserted in the record after the preceding remark further indicate the change in burden which was intended.

"I am strongly in favor of the legislation now before you to require industry, rather than the Federal Government, to shoulder the burden of proof in connection with the marketing of pesticides which may be unsafe for use as intended.

* * * * *

"The burden of proof of safety should always be on the manufacturer. . . . We must close any loopholes in the law which permit manufacturers to market products they cannot prove are safe in use in the manner intended. The bur-

legislative comment concerned new registration rather than cancellation of existing registrations, but we do not believe the statute was intended to differentiate between the two situations.[38] In view of the agency's continuing obligation to review the propriety of existing registrations, we are also satisfied that the purpose of the 1964 amendment is applicable to cancellation proceedings. The Examiner properly held that Stearns should assume the burden of proving that its registrations complied with the statute.[39]

We must therefore decide whether petitioner proved a *prima facie* case and, if so, whether the right to continue the registration was overcome by respondent's evidence. These issues require identification of the statutory standards for registration.

IV.

To be eligible for the registration under FIFRA, the product must be "an economic poison."[40] The statute has no application to products which are completely safe, or to products like aspirin

den of proof should not rest on the Government, because great damage can be done during the period the Government is developing the data necessary to remove a product which should not be marketed."

38. Actually, there are three separate points in the registration process at which the burden of proof question could arise: (1) the initial registration, (2) cancellation or refusal to reregister at the end of the initial or a subsequent 5-year registration period, and (3) cancellation during the term of a registration. Even petitioner concedes that the burden at the time of initial registration is upon the registrant—given the legislative history it could hardly be argued otherwise. See notes 32 and 37, *supra*. The statute, 7 U.S.C. § 135b(f), provides for the cancellation in situation (2) above "unless the registrant . . . requests . . . that such registration be continued in effect." The fact that the statute requires the registrant to request reregistration clearly implies that the burden in situation (2) is the same as in (1). If a presumption of proper use at the end of a 5-year period does not shift the burden of proof in situation (2), we think there is even less reason to shift the burden in the middle of a 5-year term if the Administrator should then become aware of previously unknown risks associated with the use of a product. Since we see no reason why the location of the burden of proof should depend on the timing of the Administrator's first awareness of a compliance problem, we are satisfied that the problem in situation (3) is comparable to (1) and (2).

39. Petitioner argues that in a cancellation rather than registration proceeding, the Administrator is the proponent of the order sought for purposes of 5 U.S.C. § 556(d) and that the regulation, *supra*, note 34, naming the registrant as the "proponent" is therefore invalid. Section 556(d) provides:

"Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof."

Even if the Administrator is the "proponent" of a cancellation order, the location of this burden is "otherwise provided by statute." Specifically, we read FIFRA itself as requiring that the burden of proof be on the registrant whether in a proceeding for initial registration or in a cancellation proceeding. The statutory language of 7 U.S.C. § 135b(c), taken with the clear intent to shift the pre-1964 burden of proof, cannot properly be read as providing for any distinction between registration and cancellation. The advisory committee, hearing and review provisions apply to both situations, and the concern with safety when used as directed expressed by Congress cannot be reconciled with a theory which would place the burden of proof on the government. Whether the Administrator discovers the hazard at the time of registration or later, Congress intended that the registrant have the burden of proving compliance with the provisions of the statute. *Accord*, Environmental Defense Fund, Inc. v. Ruckleshaus, 142 U.S.App.D.C. 74, 439 F.2d 584, 593 (1971).

40. "The term 'economic poison' means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living man or other animals, which the Secretary shall declare to be a pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant." 7 U.S.C. § 135(a).

and detergents which are safe enough in normal use but endanger children when used negligently. Thus, the first element of a registrant's *prima facie* case is proof that his product is dangerous; by hypothesis a poison is not completely safe.

The poison may not be registered if it is either "adulterated" or "misbranded." These terms embody more than one standard.

[5, 6] First, the product must be effective; more precisely, it must be at least as effective as the registrant claims it to be. Since all economic poisons are intended to kill some form of plant or animal life, in a sense the statute includes a minimum standard of deadliness. Petitioner's uncontradicted evidence of the effectiveness of its product met that standard.

Second, the product must satisfy certain safety standards. Although the definition of the term "adulterated" in other legislation embodies safety considerations,[41] in FIFRA it is the definition of the term "misbranded" that identifies the statutory standards of product safety. There are slight variations in the language used in different subsections of the Act, but two principal standards are identified: (1) the label accompanying the product must contain directions for use and a warning or caution statement which *"if complied with* [is] adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals";[42] and (2) an insecticide, nematocide, fungicide, or herbicide (but not a rodenticide), is misbranded if "when used as directed or *in accordance with commonly recognized practice* it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds to which it is applied, or to the person applying such economic poison."[43] The italicized phrases are those most relevant to the issues in this case.

[7] The first of these standards focuses on the safety of the product when used in compliance with directions. We think petitioner's evidence of a long history of use of Stearns Paste, involving broad distribution and numerous repeat orders, coupled with the absence of claims or evidence that injury had actually resulted from use of the product in compliance with directions, was sufficient to make a *prima facie* showing of satisfaction of this statutory standard.

[8] The second standard relates to the use of Stearns Paste as a roach and water bug killer. For this use, the directions specify pieces of paper, rather than scraps of food, as bait. It was therefore less hazardous than when used as a rodenticide. Moreover, from petitioner's evidence it would be reasonable to infer that the "commonly recognized practice" in applying Stearns Paste was consistent with the directions on the label. Accordingly, we believe petitioner also made a *prima facie* showing of compliance with this standard.

Petitioner's *prima facie* case was, of course, subject to being overcome by respondent's evidence of misbranding. Whether it has been overcome in this case depends largely on a proper formulation of the standard for finding a violation of FIFRA. Respondent, in effect, relies on a substantive standard of product safety which has little, if any, relevance to the contents of the label.[44] Respondent states the test thusly:

> "Thus, the final decision with respect to initial or continued registration of

41. Compare, for example, the language of § 135(z) (2) of FIFRA with the definitions of adulteration in the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 342 and 351, and the misbranding provisions of the same statute, 21 U.S.C. §§ 343 and 352.

42. 7 U.S.C. § 135(z) (2) (d) (emphasis added). See also § 135(z) (2) (c), *supra*, note 3.

43. 7 U.S.C. § 135(z) (2) (g) (emphasis added).

44. In contrast, consider the following comment by Senator Ribicoff: "The Federal pest control law has been described by those who administer it as being 'basically a labeling law.'" 109 Cong.Rec. 16446 (1963).

a product depends on the intricate balance struck between the benefits and dangers to the public health and welfare resulting from its use. More specifically, the Administrator must determine and weigh (1) the nature and magnitude of the foreseeable hazards associated with use of a particular product against (2) the nature of the benefit conferred by the use of the product, or, put another way, against the magnitude of the social cost of foregoing the use of the product."[45]

[9] Respondent explains that this test finds its source in the opinion of the Court of Appeals for the District of Columbia in Environmental Defense Fund, Inc. v. Ruckelshaus, 142 U.S.App. D.C. 74, 439 F.2d 584, 594 (1971), rather than in language employed by Congress.[46] An important distinction between *Ruckelshaus* and this case should be noted. *Ruckelshaus* involved possible cancellation of the registration of DDT, an insecticide which has an impact on the environment even when used in complete conformity with the manufacturer's directions.[47] That product, when properly used, has known benefits and a potential for harm that is not precisely known. To determine whether DDT is "injurious to man" requires, as the District of Columbia Circuit has fairly stated, a delicate balancing of its benefits against its adverse effects.[48] Does the net result constitute injury to man within the meaning of FIFRA? If so, it is misbranded. In short, we think the standard as stated by respondent gives proper effect to the statutory language if used to measure the net injury resulting from use of an economic poison in compliance with directions.

[10] A different situation is presented when the harm is entirely, or at least primarily, attributable to misuse of the product. To apply respondent's balancing test to such a situation is to ignore completely the concept of misbranding. Although it is consistent with the statutory language and purpose to apply a substantive standard of product safety to the use of a product in compliance with its manufacturer's directions, there is no statutory support for the application of that standard to misuse of a product. Without such support, the formulation of substantive standards of product safety by an administrative agency expands the scope of administrative discretion beyond permissible limits.

There are other objections to respondent's application of the "intricate balance" test to the problem presented by this case. In the DDT situation, the benefits of the poison are ascertainable with a reasonable degree of certainty; it is the other side of the balance that is difficult to weigh accurately. Moreover, the injury from DDT is to "man" in a collective sense—that is, to the total environment in which he lives. The obverse situation is present here. The cost to the community at large of de-

45. Respondent's brief, p. 10. Respondent explained in a footnote that the test which it applies is not explicitly set forth in the statute, stating:

> "The FIFRA itself does not explicitly provide that, prior to a cancellation or suspension, the Administrator must or should consider the benefits derived from use of a pesticide. It would, however, be unreasonable to ban the interstate distribution of a pesticide on grounds of hazard to public health or the environment if in fact such a ban would itself cause the greater hazards (*e. g.*, the unleashing of disease vectors). In reliance upon the Act's legislative history and recent judicial interpretations, the Environmental Protection Agency has now unequivocally taken the position that Congress has, in the Act, granted the Agency sufficient discretion to weigh the hazards and benefits from use of a pesticide in making a final cancellation determination. . . ."

46. See note 45, *supra*.

47. *Cf.* Environmental Defense Fund, Inc. v. United States Dept. of H.E.W., 138 U.S.App.D.C. 381, 428 F.2d 1083 (1970); Environmental Defense Fund, Inc. v. Hardin, 138 U.S.App.D.C. 391, 428 F.2d 1093 (1970).

48. 439 F.2d at 594.

priving the homeowner and apartment dweller of an inexpensive rat poison cannot be measured on this record.[49] The injury which respondent seeks to avoid in this proceeding is to specific individuals rather than to the total environment. That harm is largely attributable to willful misuse (in the case of suicide ingestions), wanton recklessness, or at least negligent behavior. Thus, on one side of the balance is a relatively small number of incidents of individual harm resulting from misuse by the comparative few; on the other side is the cost of depriving the prudent majority of a known but only vaguely defined benefit. In short, the conflicting interests are not identified sufficiently in the findings to determine whether the counterbalancing factors have been assigned proper weights.

The "intricate balance" test is inappropriately applied in this case for yet another reason. The Hearing Examiner placed important reliance on the absence of adequate information about the incidence of phosphorous paste poisonings and the actual circumstances in which it occurs without making any attempt to classify the data, either by estimate, by extrapolation, or by specific example, as between ingestions of registered and unregistered products, as between products purchased at retail and paste applied by commercial exterminators, or even as between misuse and use in accordance with instructions. He did endeavor, in discussing the National Clearinghouse data, to identify the portion of total ingestions which involved petitioner's product, and he also identified those examples of deliberate misuse that fell in the suicide category. But his affirmative reliance on the lack of adequate information as possibly supporting an inference that the danger may be ten times as great as the available data actually disclosed, cannot satisfy the test characterized as an "intricate balance." Furthermore, the Judicial Officer's findings contain no analysis of the actual or potential injury to man resulting from rats and roaches.

[11] In any balancing test used to measure the acceptability of public sale of poisonous substances, it is imperative that the emotional impact of dramatic but unfortunate tragedies not be permitted to weigh too heavily on the scales. The spectacle of a young child suffering a violent death by poisoning offers a compelling justification for avoiding the danger of recurrence by banning future use of the poison forthwith.[50] Unfortunately, however, such tragedies are a common occurrence in today's complex society and must be appraised as dispassionately as possible. Whether they justify a particular prohibition involves a policy choice which, under our scheme of government, must be made by a legislature or by an agency to which the legislature has delegated the responsibility for making principled decisions in accordance with its basic statement of pol-

49. The Hearing Examiner made no attempt to define this cost except by noting that other effective rodenticides are available. But he found neither equal effectiveness nor equal availability. Economics was apparently not considered (see note 11, *supra)* even though economics might be a very important consideration in determining equal availability; the two judges of this court who have spoken to the merits of the problem have indicated that some consideration of economics would be appropriate. Nor-Am Agricultural Products, Inc. v. Hardin, 435 F.2d 1133, 1135 (opinion of Judge Pell), 1146 (concurring opinion of Chief Judge Swygert) (7th Cir. 1970), reversed on rehearing *en banc* on procedural grounds, 435 F.2d 1151, 1163 (dissenting opinion of Judge Pell). Moreover, if consideration is given to the possibility that respondent's standards applied on an evenhanded basis might require the banning of other rat poisons as well, there is an even greater uncertainty respecting the cost of the cancellations to the community. Cancellation action has already been initiated or considered against some alternative insecticides (Tr. 204).

50. Equally tragic and dramatic instances might fall on the other side of the balance if every child who has suffered a rat bite could describe his nightmares.

icy. The fact that a legislature may react slowly to obvious dangers, such as the holocaust on our highways,[51] the creeping infection of our environment, and the consumption of deleterious substances in the home, cannot justify an agency's policy determinations that are not authorized by statute.

[12] The danger of misuse is, of course, a proper subject of regulatory concern. But unless the statutory concept of misbranding has itself been misbranded, under FIFRA that danger must be related to the form of the label.[52] Neither the language of the statute nor its legislative history focuses directly on the problem of misuse, but there can be no doubt that the agency was intended to supervise the form and content of labels.[53] An obvious purpose of such supervision is to minimize the risk of misuse.

[13, 14] The Hearing Examiner did note the relevance of the label in certain of his conclusions. Thus, he stated that the label warnings had "not been adequate to prevent injury to living man" since injuries and fatalities had actually been caused by phosphorous paste products.[54] He thus implied that a product might be misbranded whenever its label failed to prevent injury to man. Such a standard of total prevention is manifestly too strict; it would require the agency to prohibit the use of phosphorous paste by commercial pest control operators, and would be broad enough to authorize cancellation of any poison registration whenever an incident involving fatal misuse occurred.[55]

51. "But even the best legislation cannot solve the whole problem. Pesticides would seem to belong in the same category as automobiles—with great potential for good or harm, depending upon how they are used." Galton, Great Debate over Pests and Pesticides, 109 Cong.Rec. 6581, 6583 (1953), reprinted from the New York Times of April 14, 1963.

See also separate opinion of Mr. Justice Blackmun in Perez v. Campbell, 402 U.S. 637, 657, 672, 91 S.Ct. 1704, 29 L.Ed.2d 233. He said at p. 657, 91 S.Ct. at p. 1715:

"The slaughter on the highways of this Nation exceeds the death toll of all our wars. The country is fragmented about the current conflict in Southeast Asia, but I detect little genuine public concern about what takes place in our very midst and on our daily travel routes."

52. As Mr. Justice Frankfurter pointed out:

"In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." 62 Cases More or Less, Each Containing Six Jars of Jam, etc. v. United States, 340 U.S. 593, 600, 71 S.Ct. 515, 520, 95 L.Ed. 645.

53. See notes 33 and 44, *supra*.

54. "Such warning, if complied with, must be adequate to *prevent* injury to living man. The record raises serious doubts whether such warnings can be complied with. Also, that the warnings have not been adequate to prevent injury to living man is apparent from the record of injury and fatality caused by phosphorus paste products, including registrant's." A. 273 (emphasis in original).

Such a strict test was repudiated in the original panel's opinion in Nor-Am Agricultural Products, Inc. v. Hardin, 435 F.2d 1133, 1137, reversed on procedural grounds on rehearing *en banc*, 435 F.2d 1151 (7th Cir. 1970). See also the excerpts from *Nor-Am* in note 55, *infra*.

55. Cf. Nor-Am Agricultural Products, Inc. v. Hardin, 435 F.2d 1133, reversed on procedural grounds on rehearing *en banc*, 435 F.2d 1151 (7th Cir. 1970). Only two members of the Court reached the substantive issue, and both recognized the difference between harm resulting from proper use and harm resulting from occasional misuse. Chief Judge Swygert wrote in concurring in the original decision:

"The Alamogordo incident was a freak occurrence, the result of the combined negligence of the granary where the seed was treated and the head of the afflicted family. The tragic events came about through misuse rather than normal use of the treated grain. Accordingly, the district court correctly concluded, in my opinion, that the suspension order, based on this single, abnormal incident, was an arbitrary exercise of the Secretary's emergency authority under the statute." *Id.* at 1146.

Judge Pell wrote in dissenting from the *en banc* decision:

"In this country I dare say there are very few barns, medicine chests, or even

[15] We do not believe an isolated incident of misuse causing harm, or even death, to a particular individual is contemplated by the "injury to man" language in the statute. The word "man" is used in a collective sense, or perhaps with a typical connotation, as in the "reasonable and prudent man" concept familiar to negligence lawyers. In that sense the adequacy of the label may be judged by its tendency to protect against misuse. The judgment appropriately takes into account the toxicity of the product, the clarity of the warnings and the directions, and the ability of the user or purchaser to comprehend and thereby to avoid misuse.

[16] To a limited extent these factors were considered by the Hearing Examiner; but again, we believe he implicitly adopted a test which was more strict than Congress intended. He appears to have accepted the expert's view that "the general public" is incapable of following instructions. That view would justify—indeed, might require—exclusion of all economic poisons from home use. Of greater importance, it is contrary to the premise which Congress must have accepted in the enactment of FIFRA. A statute which is primarily a regulation of labels necessarily assumes that the general public does heed warnings. We believe a fair respect for the statute requires rejection of a test of misbranding predicated on total illiteracy or universal disregard of instructions.

[17–19] The adequacy of a label will, of course, be affected by the nature of the message to be conveyed and the ability of the reader to comprehend its meaning. Thus, if a product is not safe unless intricate or esoteric instructions printed in small type are followed with precision, use by laymen, even if reasonably careful, would create an obvious risk of injury to man.[56] On the other hand, a conspicuous "POISON—KEEP AWAY FROM CHILDREN" warning in large red letters, prominently accompanied by skull and crossbones symbols, conveys a message which even the illiterate can understand. Disregard of such a simple warning would certainly constitute gross negligence.

[20] It is not our function, however, to articulate in the first instance the standards which may support a finding of misbranding based primarily on evidence of misuse.[57] The agency must di-

kitchen cupboards which do not have products contained therein which would be extremely detrimental to people if misused. In the case on appeal the evidence amply supports a misuse of the product in the Alamogordo situation. The fact that misuse may result in damage does not in my opinion make a product imminently hazardous in the absence of an evidentiary showing that such misuse is frequent or was reasonably likely to occur." Id. at 1164.

The case was ultimately decided on procedural grounds unrelated to the obvious distinction between proper use and misuse identified by those two judges.

56. Similarly, in our view, respondent has adequate power to require the elimination of possible ambiguity in the labeling of a dangerous product. Thus, for example, if a warning to keep a product away from children was contradicted by a label directing its use in places normally frequented by children, he could require appropriate revisions, such as a more emphatic warning against use if there is any possibility of access by children. In this connection it should be noted that even in tragic instances of "misuse" by small children, the relevant "misuse" to be avoided is that of adults who fail to take proper precaution against the danger that children may have access to the product. If an adult purchaser's use of a product in accordance with directions creates a significant danger of harm to children, obviously the registrant could not defend on the ground that the child was guilty of "misuse."

57. An example of a possible standard is suggested in footnote 6 to the opinion of the Judicial Officer in the proceeding entitled In re Hari Kari Lindane Pellets et al., I.F.&R. Docket No. 6, in which he stated: "Counsel's argument that all lindane products pose a threat of accidental ingestion by children was apparently dismissed on the ground that the Act requires only a label that will be a caution to the hypothetical 'prudent man.'"

rect its attention to that problem in its administration of a statute which is principally a regulation of labels rather than substances. We are persuaded that it has not yet done so but instead has indiscriminately applied a balancing test which is appropriate as a measure of proper use to this case which primarily involves misuse.

We express no opinion on whether the evidence in this record discloses such a probability of misuse of petitioner's product that a finding of "misbranded" would be supportable under standards consistent with FIFRA. Nor, of course, do we express any opinion on the policy issue of whether phosphorous paste should be banned from the home environment regardless of whether or not the products are misbranded within the meaning of FIFRA. We are persuaded, however, that the tests of misbranding, to the extent that they have been articulated, employed in this proceeding go beyond the authority which Congress has delegated to the agency in FIFRA.

[21, 22] In reaching this conclusion we have considered respondent's reliance on the "commonly recognized practice" phrase found in § 135(z) (2) (g), as well as the standard which assumes use in compliance with directions. Perhaps the phrase indicates that whenever misuse occurs with sufficient frequency to be considered a common practice, a finding of misbranding is required. Such an interpretation, however, would attach no significance to the word "recognized." We believe a fair reading of the phrase relates to common practices which are "recognized" in the sense that they are approved by widespread custom or practice.[58] In this case there has been no finding that misuse of Stearns Paste is either a common practice or a commonly recognized practice; furthermore, this provision would be inapplicable to the use of the paste as a rat poison, since subsection (g) does not apply to rodenticides.

[23] We therefore hold that the cancellation orders must be set aside. After developing and articulating standards consistent with the authority delegated by FIFRA for determining when a label inadequately avoids the danger of harmful misuse, respondent may again propose cancellation of petitioner's registrations. Since the propriety of adducing additional evidence cannot be determined until the standards have been articulated, we express no view on whether or not the record should be reopened. We merely hold that petitioner's *prima facie* case has not yet been overcome.

Or, as a Hearing Examiner has stated it:

"The labeling of an economic poison deals with the means by which communication is established between the registrant and the user. In bulk, that means a communication by language; and sometimes by symbols. The first step to be taken is a determination of the communicatee—must labels be addressed to those of all ages; to those of all degrees of understanding—, etc. As I see it, FIFRA requires a labeling that has as its communicatee the well-known reasonably-prudent-man. If labeling can be readily and clearly understood by the reasonably prudent man it should suffice to meet FIFRA's obligation to provide protection in the use of an economic poison. . . . ." In re Continental Chemiste Corp., I.F.&R. Docket No. 5 (Sept. 20, 1971), p. 9.

We, of course, express no opinion on these or other possible standards.

58. Frequency of misuse might nevertheless demonstrate that the warning statements required by § 135(z) (2) (d) might be inadequate. See the excerpt from Judge Pell's dissent in *Nor-Am* quoted in note 55, *supra*.

sive term 'should," but they also used the improper terms "will" and "cannot," which rendered them erroneous under the substantive law of the Arizona Constitution. The jury could have been misled or confused over whether contributory negligence was a mandatory or permissive consideration. Subsequently, the trial judge specifically called the jury's attention to the error and to the correct law of the State of Arizona. He distinctly and particularly pointed out what the law was and, in our opinion, left no doubt in the minds of the members of the jury on that point. Clear and unmistakable words were used in his curative instructions, and the error itself was not repeated or emphasized.

[14, 15] Accordingly, we hold that the trial judge's erroneous instructions were properly and effectively cured. To follow appellants' advocacy of a rule of absolute incurability of an erroneous instruction on contributory negligence would not only frustrate the purpose of Rule 51 of the Federal Rules of Civil Procedure, but would also diminish the integrity of the federal jury trial system.

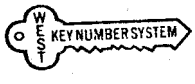
[16, 17] Further, we are not persuaded that the curative instructions of the trial judge unduly emphasized contributory negligence to the jury. The first curative instruction, although necessary to properly state the Arizona law, was concise in pointing out the error in one sentence and correcting it in another. The second curative instruction was also concise and repeated the correct statement on contributory negligence merely in the context of an instruction on proximate cause, the instruction having been requested by appellants. It may be observed that there is no requirement that a charge on proximate cause accompany each charge on contributory negligence. Bass v. Dehner, 103 F.2d 28, 35 (10th Cir.), cert. denied, 308 U.S. 580, 60 S.Ct. 100 84 L.Ed. 486 (1939). Considering the instructions as a whole as they were finally presented to the jury, we find no error.

Family Purpose Doctrine

[18, 19] The remaining contention of appellants is that the trial judge erred in directing a verdict in favor of the defendant-driver's parents on the basis that the defendant-driver's parents were entitled to judgment as a matter of law under the family purpose doctrine. That doctrine places derivative liability upon a family head who controls the use of or furnishes an automobile to a member of the family. Pesqueira [sic] v. Talbot, 7 Ariz.App. 476, 441 P.2d 73 (1968). However, in the absence of primary liability, there can be no derivative liability. Thus, the propriety of the directed verdict has been rendered moot by our affirmance of the judgment of no primary liability.

The judgment of the district court is affirmed.

Affirmed.



STREAM POLLUTION CONTROL BOARD OF the STATE OF INDIANA, Plaintiff-Appellee, and Zarko Sekerez, Proposed Intervenor, Plaintiff-Appellant,

v.

UNITED STATES STEEL CORPORATION, Defendant-Appellee.

No. 74–1244.

United States Court of Appeals, Seventh Circuit.

Argued Nov. 20, 1975.

Decided March 14, 1975.

As Amended March 24, 1975.

State Stream Pollution Control Board brought a common-law public nuisance action against a steel corporation.

A private citizen moved to intervene. The United States District Court for the Northern District of Indiana, Hammond Division, Allen Sharp, J., 62 F.R.D. 31, denied motion to intervene, and private citizen appealed. The Court of Appeals, Stevens, Circuit Judge, held that complaint of the Board, which sought to abate pollution of the Grand Calumet river, was sufficient to give district court jurisdiction to decide whether the Board was entitled to some relief as a matter of federal common law, and that such action was not an action to require compliance with a "standard, limitation or order" within meaning of 1972 Federal Water Pollution Control Act, and thus private citizen was not entitled to intervene.

Affirmed.

1. Courts ⇐405(2)

Question whether district court had jurisdiction of underlying claim would be answered by reference to allegations in the amended complaint, unaided by additional allegations in pleadings submitted in support of motion to intervene. Federal Water Pollution Control Act Amendments of 1972, §§ 101 et seq., 505(a), (b)(1)(B), 33 U.S.C.A. §§ 1251 et seq., 1365(a), (b)(1)(B).

2. Courts ⇐284(2)

Federal question jurisdiction will support claims founded upon federal common law as well as those of a statutory origin. 28 U.S.C.A. § 1331(a).

3. Navigable Waters ⇐35

Complaint of state Stream Pollution Control Board, which sought to abate pollution of the Grand Calumet river, and which alleged that defendant's industrial plant had discharged cyanide and ammonia nitrogen into the river in quantities exceeding limits specified by the Board's regulations, was sufficient to give district court jurisdiction to decide whether the Board was entitled to some relief as a matter of federal common law.

4. Federal Civil Procedure ⇐315

State Stream Pollution Control Board's action to abate a nuisance as a matter of federal common law was not an action to require compliance with a "standard, limitation or order" within meaning of 1972 Federal Water Pollution Control Act, and thus private citizen was not entitled to intervene. Federal Water Pollution Control Act Amendments of 1972, §§ 301(a), 505(b)(1)(B), (f), 33 U.S.C.A. §§ 1311(a), 1365(b)(1)(B), (f).

See publication Words and Phrases for other judicial constructions and definitions.

5. Navigable Waters ⇐35

Congress, in enacting Federal Water Pollution Control Act Amendments of 1972, intended to require step-by-step improvement in quality of discharged effluent, rather than a zig-zag course with total purity demanded forthwith only to be succeeded by varying stages of impurity. Federal Water Pollution Control Act Amendments of 1972, §§ 101(a)(1), 301(a), (b)(1)(A)(i), (2)(A)(i), 505(f), (f)(1–6), 33 U.S.C.A. §§ 1251(a)(1), 1311(a), (b)(1)(A)(i), (2)(A)(i), 1365(f), (f)(1–6).

6. Navigable Waters ⇐35

Congress, in enacting Federal Water Pollution Control Act Amendments of 1972, carefully created a two-phased program for moving American industry toward eventual goal of a total absence of all water pollution by 1985, and did not intend that, until administrator of federal Environmental Protection Agency promulgated 1977 emission standards, any discharge was to be unlawful. Federal Water Pollution Control Act Amendments of 1972, §§ 101(a)(1), 301(b)(1)(A)(i), (2)(A)(i), 33 U.S.C.A. §§ 1251(a)(1), 1311(b)(1)(A)(i), (2)(A)(i).

Zarko Sekerez, pro se.

Theodore L. Sendak, Atty. Gen., Michael T. Schaefer, Deputy Atty. Gen., Indianapolis, Ind., Henry L. Pitts, Chicago, Ill., G. Edward McHie, Hammond, Ind., for appellee.

Before STEVENS, SPRECHER and TONE, Circuit Judges.

STEVENS, Circuit Judge.

Appellant, a private citizen, asks us to reverse an order denying his motion to intervene in a common law public nuisance action brought by the Stream Pollution Control Board of the State of Indiana against U. S. Steel Corporation. The questions presented are (1) whether the federal district court has jurisdiction of the underlying nonstatutory claim and, if so, (2) whether appellant has a statutory right to intervene pursuant to § 505(b)(1)(B) of the Federal Water Pollution Control Act Amendments of 1972.[1]

The Board's amended complaint invokes the district court's federal question jurisdiction pursuant to 28 U.S.C. § 1331(a).[2] It characterizes this case as "an action to abate pollution of the Grand Calumet River, a navigable stream and tributary of Lake Michigan, a body of interstate water." Specifically, the Board alleges that defendant's industrial plant in Gary, Indiana, has discharged cyanide and ammonia nitrogen into the river in quantities which exceed the limits specified by the Board's regulations.[3] In its prayer for relief, the

1. Pub.L.No.92–500, 86 Stat. 816. Section 505(b)(1)(B) is codified as 33 U.S.C. § 1365(b)(1)(B) (Supp. II, 1972). Because of their relevance, we quote subparagraphs (a) and (b) of § 1365 in full:

"§ 1365. Citizen suits.

(a) Authorization; jurisdiction.

Except as provided in subsection (b) of this section, any citizen may commence a civil action on his own behalf—

(1) against any person (including (i) the United States, and (ii) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of (A) an effluent standard or limitation under this chapter or (B) an order issued by the Administrator or a State with respect to such a standard or limitation, or

(2) against the Administrator where there is alleged a failure of the Administrator to perform any act or duty under this chapter which is not discretionary with the Administrator.

The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such an effluent standard or limitation, or such an order, or to order the Administrator to perform such act or duty, as the case may be, and to apply any appropriate civil penalties under section 1319(d) of this title.

(b) Notice.

No action may be commenced—

(1) under subsection (a)(1) of this section—

(A) prior to sixty days after the plaintiff has given notice of the alleged violation (i) to the Administrator, (ii) to the State in which the alleged violation occurs, and (iii) to any alleged violator of the standard, limitation, or order, or

(B) if the Administrator or State has commenced and is diligently prosecuting a civil or criminal action in a court of the United States, or a State to require compliance with the standard, limitation, or order, but in any such action in a court of the United States any citizen may intervene as a matter of right.

(2) under subsection (a)(2) of this section prior to sixty days after the plaintiff has given notice of such action to the Administrator,

except that such action may be brought immediately after such notification in the case of an action under this section respecting a violation of sections 1316 and 1317(a) of this title. Notice under this subsection shall be given in such manner as the Administrator shall prescribe by regulation."

2. That section provides:

"(a) The district courts shall have original jurisdiction of all civil actions wherein the matter in controversy exceeds the sum or value of $10,000, exclusive of interest and costs, and arises under the Constitution, laws, or treaties of the United States."

Paragraphs 1 and 3 of the amended complaint allege that the amount in controversy exceeds $10,000, exclusive of interest and costs.

3. For several years the Board has been trying to compel defendant to minimize these discharges. In 1967 it promulgated water quality standards which it claims U. S. Steel has violated. In 1970 the Board held an administrative hearing and ordered defendant to install new water treatment facilities; its order was set aside by the Indiana courts as not supported by adequate findings of fact.

In 1973 the Board commenced this litigation. In its original complaint it invoked the jurisdiction of the federal court pursuant to 28 U.S.C. § 1332, alleging that the parties were of diverse citizenship. In that complaint, the Board alleged violations of its own regulations and asked the federal court to impose the statutory penalties authorized by Indiana law.

Board asks the federal court to order defendant to abate its pollution of the Grand Calumet River, to enter judgment in the amount of $80,000 (representing penalties authorized by Indiana statute), and to grant "all other proper relief in the premises."

Appellant, a private citizen of Indiana, moved to intervene, alleging that his interests in the waters of Lake Michigan and the environment of the State of Indiana may be adversely affected by these proceedings. He adopted the Board's allegations and, in addition, alleged that defendant was causing oil to accumulate in the river and that its discharges were polluting Lake Michigan.[4] He claimed "an unconditional right to intervene" pursuant to § 505(b)(1)(B).

The district court denied the motion to intervene, holding that the nuisance action was not brought to require compliance with an effluent standard or limitation promulgated pursuant to the Federal Water Pollution Control Act Amendments of 1972 (hereinafter "the 1972 Act"), and therefore that § 505(b)(1)(B) of that Act did not grant appellant a right to intervene. The district court also denied U. S. Steel's motion to dismiss, holding that the jurisdictional question was answered by the unanimous opinion of the Supreme Court in Illinois v. City of Milwaukee, 406 U.S. 91, 92 S.Ct. 1385, 31 L.Ed.2d 712. We affirm.

I.

[1] Before reaching the question whether appellant has a statutory right to intervene we must decide whether the district court has jurisdiction of the underlying claim. For, as defendant argues, if it is apparent from the record that jurisdiction is lacking, we must order the action dismissed.[5] Moreover, the jurisdictional question must be answered by reference to the allegations in the amended complaint, unaided by the additional allegations in pleadings submitted in support of the motion to intervene. *See* Pianta v. H. M. Reich Co., Inc., 77 F.2d 888, 890 (2d Cir. 1935).

The Board's amended complaint, unlike appellant's pleadings, contains no allegation of pollution of Lake Michigan. Nor do the pleadings contain any allegation that the interests of any sovereign, or of the citizens of any state other than Indiana, have been affected by defendant's discharges. The jurisdictional question in this case is therefore not necessarily answered by the holding of the Supreme Court in Illinois v. City of Milwaukee, 406 U.S. 91, 92 S.Ct. 1385, 31 L.Ed.2d 712.

[2] That case does, however, unequivocally confirm " that § 1331 jurisdiction will support claims founded upon federal common law as well as those of a statutory origin." *Id.* at 100, 92 S.Ct. at 1391. Moreover, that opinion expressly authorizes the federal courts to fashion a federal common law of public nuisance to resolve controversies involving the impairment of the environmental interests of one state by sources outside its domain.[6]

Subsequently, the Board filed the amended complaint which is before us, which includes the "federal common law" nuisance claim discussed in the text.

4. For example, in his "Amended Pleading of Intervenor," appellant alleged:

"(12) Petitioner is a person having an interest in the waters of Lake Michigan in that he uses said waters for fishing and said interest is being adversely affected in that said waters are being polluted by the defendant and the fish are being poisoned by the defendant.

"(13) Petitioner is a person having an interest which is or may be adversely affected in that the discharge of acids and other industrial wastes into the waters of Lake Michigan by the defendant is a threat to petitioner's health and the health of his family."

5. *See* Carson v. Allied News Co., 511 F.2d 22 (7th Cir. 1975).

6. *See, e. g.,* the Court's express approval of the decision in State of Texas v. Pankey, 441 F.2d 236 (10th Cir. 1971). *See* 406 U.S. at 103, 107 n. 9, 92 S.Ct. 1385.

Of greater relevance to this case are the repeated references to the controlling importance of federal law applicable to the pollution of "interstate or navigable waters."[7] Those references may well imply that the federal common law of public nuisance extends to all of our navigable waters, and perhaps to all tributaries of interstate waters. We cannot tell from the Court's opinion, however, whether, apart from statute, the federal interest in navigability would support a nuisance action without any allegation of interference with navigation, or whether the interest in the purity of interstate bodies of water is sufficient to justify nonstatutory federal protection of all tributaries. We need not, however, resolve such questions to decide the precise jurisdictional issue before us.

The question we must decide is not whether the amended complaint states a cause of action for which relief can be granted, but rather whether the complaint raises substantial questions which only a federal court may finally answer. As the Supreme Court held in Bell v. Hood:

> Whether the complaint states a cause of action on which relief could be granted is a question of law and just as issues of fact it must be decided after and not before the court has assumed jurisdiction over the controversy. * * * The previously carved out exceptions are that a suit may sometimes be dismissed for want of jurisdiction where the alleged claim under the Constitution or federal statutes clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or where such a claim is wholly insubstantial and frivolous.

327 U.S. 678, 682–683, 66 S.Ct. 773, 776, 90 L.Ed. 939.

[3] The amended complaint in this case purports to state both a claim under Indiana law and a claim under federal common law. We may assume, as defendant argues, that the attempt to recover statutory penalties for violation of the Board's regulations is not a "civil action" over which the federal court would have independent jurisdiction. Nevertheless, we cannot fairly conclude from the pleading itself that the federal claim is merely colorable and asserted solely for the purpose of conferring jurisdiction on the district court to decide the state law issues. Nor, in view of the broad language used by the Supreme Court in the *City of Milwaukee* opinion, with particular reference to its emphasis on the federal interest in uniformity in dealing with the pollution of interstate or navigable waters,[8] can we characterize the Board's federal claim as "wholly insubstantial and frivolous."[9] Surely enough has been alleged to give the district court jurisdiction to decide whether the Board is entitled to some relief as a matter of federal common law.[10]

7. *Id.* at 99, 102, 104, 92 S.Ct. 1385.

8. "[I]t is not only the character of the parties that requires us to apply federal law. . . . As Mr. Justice Harlan indicated for the Court in Banco Nacional de Cuba v. Sabbatino, 376 U.S. 398, 421–427 [84 S.Ct. 923, 936–940, 11 L.Ed.2d 804], where there is an overriding federal interest in the need for a uniform rule of decision or where the controversy touches basic interests of federalism, we have fashioned federal common law." 406 U.S. at 105 n. 6, 92 S.Ct. at 1393. (Citations omitted).

9. While U. S. Steel argues that the application of this federal common law depends on the existence of a conflict between sovereigns, we note that, with one exception, the federal district courts have permitted the federal government to utilize this federal common law as a basis for pollution-abatement actions. *See* United States v. Stoeco Homes, Inc., 359 F.Supp. 672 (D.N.J.1973); United States v. United States Steel Corp., 356 F.Supp. 556 (N.D.Ill.1973); United States v. Ira S. Bushey & Sons, Inc., 346 F.Supp. 145 (D.Vt.1972). *Contra*, United States v. Lindsay, 357 F.Supp. 784 (E.D.N.Y.1973). In United States v. Lindsay, the district court stated that *City of Milwaukee* was addressed to situations involving suits between states. 357 F.Supp. at 794. The court had announced earlier, however, that it was not deciding this question at this time. 357 F.Supp. at 793–794.

10. We need not decide, consequently, whether the 1972 Amendments and the regulations promulgated thereunder have acted to "preempt the field of federal common law of nuisance," in Justice Douglas' words. 406 U.S.

The district court correctly assumed jurisdiction of the controversy. Whether it correctly held that the amended complaint stated a federal cause of action is a question which is not properly before us on this appeal.

II.

[4] Under 33 U.S.C. § 1365(b)(1)(B), appellant, as a private citizen, is entitled to intervene if, and only if, the underlying action was commenced and is being prosecuted to require compliance with a "standard, limitation, or order" within the meaning of the 1972 Act. We hold that an action to abate a nuisance as a matter of federal common law is not such an action and that the motion to intervene was therefore correctly denied.

The term "effluent standard or limitation under this chapter" is defined in subsection (f) to include "an unlawful act under subsection (a) of section 1311 of this title." [11] That subsection (i. e., § 1311(a)) provides that:

> Except as in compliance with this section and sections 1312, 1316, 1317, 1328, 1342, and 1344 of this title, the discharge of any pollutant by any person shall be unlawful.

Appellant does not argue that defendant has failed to comply with any of the enumerated sections of the Act except the remaining portion of § 1311. The other sections are plainly inapplicable.[12] The remainder of § 1311, in brief, provides a timetable for the promulgation of various effluent limitations to become effective, in some cases no later than July 1, 1977, and in others no later than July 1, 1983.[13] Appellant argues that de-

at 107, 92 S.Ct. at 1395. Prior to the promulgation of effluent limitations, this possibility had been rejected by several courts. People of the State of Illinois ex rel. Scott v. City of Milwaukee, Wisconsin, 366 F.Supp. 298, 299–301 (N.D.Ill.1973); United States v. Ira S. Bushey & Sons, Inc., 363 F.Supp. 110, 119–120 (D.Vt.1973); United States v. United States Steel Corp., 356 F.Supp. 556, 558–559 (N.D.Ill.1973).

11. Subsection (f) reads as follows:

> "For purposes of this section, the term 'effluent standard or limitation under this chapter' means (1) effective July 1, 1973, an unlawful act under subsection (a) of section 1311 of this title; (2) an effluent limitation or other limitation under section 1311 or 1312 of this title; (3) standard of performance under section 1316 of this title; (4) prohibition, effluent standard or pretreatment standards under section 1317 of this title; (5) certification under section 1341 of this title; or (6) a permit or condition thereof issued under section 1342 of this title, which is in effect under this chapter (including a requirement applicable by reason of section 1323 of this title)." 33 U.S.C. § 1365(f).

12. Section 1312 provides for the establishment of a stricter effluent limitation in areas where those defined by § 1311(b) are inadequate to maintain a water quality level "which shall assure protection of public water supplies, agricultural and industrial uses" and other important uses. No such stricter limitation has, to our knowledge, been established for this U. S. Steel facility. Thus, the reference in § 1311(a) to § 1312 is inapplicable here.

Similarly inapplicable are §§ 1316, 1317, and 1328 which provide for effluent limitations for new point sources, special toxic pollutants, and for discharges associated with an approved aquaculture project. Nor would U. S. Steel have to obtain a permit containing the standards set forth in § 1344 for the discharge of dredged or fill material.

Thus, the only sections with which U. S. Steel need comply are § 1311(b), which defines effluent limitations for existing point sources, and § 1342, which establishes a permit program to ensure the observance of § 1311(b)'s standards. The E.P.A. has, however, issued permits to major pollution sources even before the issuance of the relevant effluent limitations guidelines. *See* T. Arnold, Effluent Limitations and NPDES, 15 B.C.Ind. & Com.L.Rev. 767, 772–773 (1974); 33 U.S.C. § 1342(a)(1). Neither U. S. Steel nor Sekerez has informed us, however, that the Gary facility had in fact received a permit at the time of these discharges in early 1973. Thus, we assume that these discharges did not violate the terms of any federal permit. Similarly, as the record contains no allegation to the contrary, we assume that U. S. Steel has made proper application for a discharge permit, thus shielding it from liability for discharges in the absence of a permit under 33 U.S.C. § 1342(k). *See generally,* Natural Resources Defense Council, Inc. v. Train, 510 F.2d 692, at 696 (D.C.Cir., 1974).

13. Pursuant to 33 U.S.C. § 1314(b), the Administrator of the federal Environmental Protection Agency is responsible for promulgating guidelines to establish the effluent standards or limitations called for throughout the amendments. Section 1311(b) requires that existing point sources achieve, by 1977, an

fendant could not possibly be in compliance with any such limitation before it has been promulgated; *ergo,* he argues, before an applicable limitation takes effect, defendant is totally prohibited from discharging any pollutant into the river. Since the amended complaint seeks abatement, he therefore contends that it is an action to require compliance with the 1972 Act.[14]

On its face, § 1365(f) does not support Sekerez' position. The term "effluent standard or limitation under this chapter" is defined as an unlawful act under subsection (a) of section 1311 of Title 33 only "effective July 1, 1973." *See* n. 11, *supra.* The amended complaint herein refers to discharges by the Gary facility on April 12, April 19, April 26, and May 9, 1973, all well before the crucial July 1, 1973, date. Thus, § 1365(f)(1) is not available to Sekerez. As the relevant limitations, standards of performance, prohibitions, certifications, and permits referred to in § 1365(f)(2)–(6) either had not been promulgated as of the dates of the discharges or are not applicable here (*see* n. 12, *supra*), the underlying action cannot be one to require compliance with a standard, limitation, or order, the predicate for intervention under § 1365(b)(1)(B).

Even assuming, however, that the amended complaint can be read to refer to discharges continuing beyond July 1, 1973, and therefore into the time period to which § 1365(f)(1) applies, there are at least two reasons why appellant's argument is unacceptable. First, § 1311(a) speaks in terms of compliance with sections of the statute, rather than compliance with an effluent standard or limitation. We think defendant is in compliance with the statute as long as it does not violate any of its provisions. Since its discharges cannot violate any effluent standard or limitation until after such a standard has become effective, defendant's earlier discharges are not prohibited by the Act; defendant is therefore in compliance with the statute.[15]

[5, 6] Second, appellant's construction of the statute is dramatically at odds with the entire legislative scheme.[16] Under appellant's view, the promulgation of an effluent standard would be tantamount to a license to pollute, rather than a required curtailment of an existing in-

effluent limitation "which shall require the application of the best practicable control technology currently available" and, by 1983, an effluent limitation "which . . . shall require application of the best available technology economically achievable for such category or class, which will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants."

The effluent limitations defined in § 1311(b) are to be incorporated into the discharge permits issued each point source under 33 U.S.C. § 1342(a)(1).

At the time the underlying suit was brought by the Stream Pollution Control Board, the Administrator of the E.P.A. had not promulgated the effluent limitation guidelines that would establish the permissible emissions by the class or category of point sources of which this U. S. Steel facility is a member. Subsequently, on February 19, 1974, notice of proposed effluent limitation guidelines for the iron and steel manufacturing point source category was given. 39 Fed.Reg. 6484 (1974). These proposed limitations were adopted by the Administrator on June 28, 1974, as 40 C.F.R. Part 420. 39 Fed.Reg. 24114 (1974). We assume, arguendo, that these limitations are applicable to the source involved in this case. While 33 U.S.C. § 1314(b) had required the Administrator to adopt such regulations within one year of October 18, 1972, his failure to do so led to the issuance of a court order in Natural Resources Defense Council v. Train, 6 E.R.C. 1033 (D.D.C.1973), aff'd, 510 F.2d 692 (D.C.Cir., 1974).

14. Appellant's argument assumes that the Board's amended complaint seeks *total cessation* of defendant's discharges of cyanide and ammonia nitrogen. Although this is, at best, a doubtful reading of the amended complaint, we assume arguendo that it is a correct interpretation of the Board's prayer for relief.

15. Similarly, U. S. Steel cannot violate the terms of a discharge permit until one has been issued.

16. For a general review of the provisions of the 1972 amendments *see* Comment, The Federal Water Pollution Control Act Amendments of 1972, 1973 Wis.L.Rev. 893 (1973); Comment, the Federal Water Pollution Control Act Amendments of 1972, 14 B.C.Ind. & Com.L.Rev. 672 (1973).

dustry practice. For, under his view, discharges are totally prohibited until the effluent limitation becomes effective, and thereafter permitted in amounts not exceeding the licensed level. It is manifest that Congress intended to require step-by-step improvement in the quality of discharged effluent,[17] rather than a zigzag course with total purity demanded forthwith only to be succeeded by varying stages of impurity.

Judge Sharp's order denying the motion to intervene is

Affirmed.

UNITED STATES of America, Plaintiff-Appellee,

v.

Antonio QUESADA, Alfredo Flores, a/k/a Ali and Maritza Brezot, Defendants-Appellants.

No. 74-2881.

United States Court of Appeals, Fifth Circuit.

May 7, 1975.

Rehearing Denied June 11, 1975.

Defendants were convicted in the United States District Court for the Southern District of Florida, James Lawrence King, J., of conspiracy to receive, conceal, buy and sell unlawfully imported heroin, and they appealed. The Court of Appeals, Clark, Circuit Judge, held that defendant's allegation that he was kidnapped by government agents and brought into the United States did not defeat the district court's personal jurisdiction; that the evidence was sufficient to support the conviction; that the separate indictments of two coconspirators did not render said coconspirators unavailable to defendant as witnesses and did not bar use of their statements against defendant; and that defendants were not so prejudiced by the conduct of the Government's attorney in talking to a prosecution witness that a mistrial should have been declared or the witness' testimony stricken.

Affirmed.

1. Criminal Law ⇐99

In prosecution for conspiracy to receive, conceal, buy and sell unlawfully imported heroin, assertion that defendant was kidnapped by government agents and brought into United States could not defeat personal jurisdiction of district court, notwithstanding contention that kidnapping would violate defendant's right to be free of unlawful searches and seizures and right to due process. U.S.C.A.Const. Amends. 4, 5.

2. Conspiracy ⇐47(12)

Evidence, including testimony that defendant referred to substance distributed by him as "very best" heroin, was sufficient to sustain conviction of conspiracy to receive, conceal, buy and sell unlawfully imported heroin. Narcotic Drugs Import and Export Act, § 2(b–d, f), 42 Stat. 596 as amended.

17. The 1977 standard requires "the application of the best practicable control technology currently available," 33 U.S.C. § 1311(b)(1)(A)(i). The 1983 standard requires "application of the best available technology economically achievable for such category or class, which will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants," 33 U.S.C. § 1311(b)(2)(A)(i).

33 U.S.C. § 1251(a)(1) defines "the national goal that the discharge of pollutants into the navigable waters be eliminated by 1985."

These provisions make it clear that Congress, which very carefully created a two-phased program for moving American industry toward the eventual goal of a total absence of all water pollution by 1985, did not intend that, until the Administrator promulgated the 1977 emission standards, any discharge was to be unlawful. It would be ironic indeed if the promulgation of such standards, incorporating as they must "the best practicable control technology currently available," acted to move us away from, rather than nearer to, this eventual goal.

for a directed verdict. There was direct evidence, or evidence from which it could properly be inferred, that any other oil company refused to refinance Champion and accept it as a distributor because of the existence of the lease/leaseback agreements. To the contrary, the evidence is overwhelming that the refusals were based on the poor financial condition of Champion and its inability to reduce operating expenses—the very considerations which caused Sinclair to put it on a C.O.D. basis. The real estate building features of the lease/leaseback arrangement appear to have been the chief reason for Champion's decision to affiliate with Sinclair. During the entire time of deteriorating relations between the parties Sinclair continued to pay rent on the seven stations which Champion owned and had financed through the arrangement of which it now complains. For a portion of the time four of these stations were being operated by Sinclair rather than Champion, but Champion was building equity in them. Because of this growth in equity Champion was able to secure some financial relief by placing second mortgages on this real estate which had originally been encumbered with mortgages representing its full value.

The district court correctly determined that there was no *per se* violation of the Sherman Act and that the case did not involve an illegal tying arrangement. We find that there was no proof that the contracts and leases complained of were designed to, or did in fact, suppress interbrand competition, or otherwise result in unreasonable restraint of trade. Such proof is required in non *per se* cases. Because of our disposition of this issue we do not reach other questions which the parties have argued on appeal.

The judgment of the district court is reversed and the cause is remanded with instructions to enter judgment notwithstanding the verdict dismissing the complaint.

UNITED STATES of America,
Plaintiff-Appellee,

v.

EWIG BROS. CO., INC., a corporation, and Eugene W. Ewig, an individual,
Defendants-Appellants.

UNITED STATES of America,
Plaintiff-Appellant,

v.

VITA FOOD PRODUCTS OF ILLINOIS, INC., a corporation, and Lawrence T. Schweig, an Individual, Defendants-Appellees.

Nos. 73-1008, 73-1454.

United States Court of Appeals,
Seventh Circuit.

Argued Jan. 7, 1974.

Decided Aug. 28, 1974.

Action by United States to enjoin distribution of fish contaminated with DDT. The United States District Court for the Eastern District of Wisconsin, Myron L. Gordon, J., held that distribution of fish designed for human consumption but containing DDT in amount in excess of five parts per million would be enjoined, 353 F.Supp. 250, and defendants appealed. In second case the United States brought action seeking injunctive relief against violations of the Food, Drug, and Cosmetic Act. The United States District Court for the Northern District of Illinois, James B. Parsons, J., entered judgment for defendants, 356 F.Supp. 1213, and United States appealed. The Court of Appeals, Stevens, Circuit Judge, held that DDT and dieldrine, found in smoked chubs of defendants were "food additives," and that, since they were not protected by any tolerances, the chubs were "adulterated" as a matter of law, and that conclusion of district court that Government's AOAC method of testing for chemical residues could not be used to evaluate compliance of defendants with guidelines set forth by the Food and

Drug Administration was clearly erroneous.

Judgment in first case affirmed, judgment in second case reversed and remanded.

1. Food ⇐2

DDT is unquestionably a "pesticide chemical," as that term is defined in the Food, Drug, and Cosmetic Act. Federal Food, Drug, and Cosmetic Act, § 201(q) as amended 21 U.S.C.A. § 321(q).

See publication Words and Phrases for other judicial constructions and definitions.

2. Food ⇐5

Before processing, DDT is a "pesticide chemical" on a raw product, while after processing it is an "additive", and since there is no tolerance for DDT on fish, both before and after processing the presence of DDT causes fish to be "adulterated", without any proof that it is actually unfit as food. Federal Food, Drug, and Cosmetic Act, §§ 201, 201(s), 402, 402(a)(2)(B, C) as amended 21 U.S.C.A. §§ 321, 321(s), 342, 342(a)(2)(B, C).

See publication Words and Phrases for other judicial constructions and definitions.

3. Food ⇐5

DDT and dieldrin found in smoked chubs taken from the Great Lakes were "food additives" and, since they were not protected by any tolerances, the chubs were "adulterated" as a matter of law within meaning of the Food, Drug, and Cosmetic Act, since they contained an unsafe pesticide chemical. Federal Food, Drug, and Cosmetic Act, §§ 201, 201(s), 402, 402(a)(2)(B, C), 408 as amended 21 U.S.C.A. §§ 321, 321(s), 342, 342(a)(2)(B, C), 346a.

4. Food ⇐5

For purposes of action by United States seeking injunctive relief against violations of the Food, Drug, and Cosmetic Act, enforcement guidelines set forth in press release of the Food and Drug Administration, which stated that the interim limit of five parts per million for DDT residue would apply to all fish marketed interstate, was binding upon the Food and Drug Administration, notwithstanding the informal manner of its release, as if it were a general rule published in accord with requirements of the Administrative Procedure Act. 5 U.S.C.A. § 551 et seq.

5. Courts ⇐406.3(24)

Determination that the Government's AOAC method of testing for chemical residues could not be used to evaluate compliance of defendant corporation with guidelines set by the Food and Drug Administration was clearly erroneous.

6. Food ⇐5

Accepting the Government's AOAC method of testing for chemical residues as a proper standard for measuring residues of pesticide chemicals in fish required conclusion that Government met its burden of proving repeated violations of Federal Food and Drug Administration guidelines by defendant corporation which guidelines provided, inter alia, that the interim limit of five parts per million for DDT residues would apply to all fish marketed interstate.

Adrian P. Schoone, Racine, Wis., for appellants Ewig Bros. Inc. et al.

Gregory B. Hovendon, Chief, Consumer Affairs Section, U. S. Dept. of Justice, Washington, D. C., David J. Cannon, U. S. Atty., Milwaukee, Wis., Charles J. Raubicheck, U. S. Dept. of H. E. W., Washington, D. C., for the United States in No. 73–1008.

James R. Thompson, U. S. Atty., Gary L. Starkman and Robert B. Schaefer, Asst. U. S. Attys., Chicago, Ill., Gregory B. Hovendon, Chief, Consumer Affairs Section, U. S. Dept. of Justice, Charles J. Raubicheck, U. S. Dept. of H. E. W., Washington, D. C., for the United States in No. 73–1454.

Patrick W. O'Brien, Chicago, Ill., for Vita Food Products of Ill., Inc. et al.

Before HASTINGS, Senior Circuit Judge, and STEVENS and SPRECHER, Circuit Judges.

STEVENS, Circuit Judge.

There are two ways to state the principal question presented by these appeals. Narrowly, the issue is whether residues of DDT and dieldrin in smoked chubs are "food additives" within the meaning of § 201(s) of the Federal Food, Drug and Cosmetic Act.[1] A somewhat more disturbing way to state the same question is whether all of the fish in the Great Lakes are "adulterated" as a matter of statutory definition.[2] If they are, the Administrator[3] may have, at least for the present, virtually unbridled power to eliminate all such fish from our food supply. We therefore attach special importance to the additional questions presented in the *Vita Food* appeal. That appeal, unlike the *Ewig Bros.* appeal,[4] requires us to consider the

1. Section 201 of F.D.C.A., enacted as part of the "Food Additive Amendment of 1958," 72 Stat. 1784, is codified as 21 U.S.C. § 321. The definition of "food additive" reads as follows:

(s) The term "food additive" means 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 (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term 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 intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907, as amended and extended; or

(5) a new animal drug.

2. Section 402 of F.D.C.A., 21 U.S.C. § 342, defines adulterated food. The provisions of subparagraphs (a)(2)(B) and (a)(2)(C), which pertain, respectively, to pesticide chemicals on raw agricultural commodities and to food additives are relevant here; they are quoted in n. 11, *infra*.

3. Enforcement responsibility presently resides in the Administrator of the Environmental Protection Agency. The respective functions of the Secretary of H.E.W., the Secretary of Agriculture, and the Administrator, and the transfers effected by Reorganization Plan No. 3 of 1970, effective as of December 2, 1970, are outlined in United States v. Goodman, 486 F.2d 847, 848–849 (7th Cir. 1973).

4. The *Ewig Bros.* case was brought as a companion to complaints filed against five other defendants which distributed raw chubs, as opposed to the smoked chubs distributed by Ewig. In all six cases, the parties stipulated that the quantity of DDT in the chubs exceeded the informal guidelines, and, in the five raw chub cases, that DDT was a "pesticide chemical" and that the fish were "raw agricultural commodities" within the meaning of § 201 of F.D.C.A. (see 21 U.S.C. § 321(q) and (r)). In all cases Judge Gordon rejected the defendants' argument that the Administrator was required by statute to establish tolerance limits for DDT in fish before he could claim that the presence of DDT residues resulted in adulteration. In the *Ewig* case, Judge Gordon also held that DDT in the processed chubs is a food additive. He entered permanent injunctions in all six cases.

On September 29, 1973, we affirmed the judgments in the five cases involving raw chubs and entered an order holding the *Ewig* appeal for decision with *Vita Food*. See United States v. Goodman, 486 F.2d 847, 849 n. 10. In that case we held that the Administrator is not required to establish by regulation permissible tolerances of DDT and its derivatives before initiating enforcement proceedings or obtaining injunctive relief in such a proceeding. Judge Sprecher's opinion in that case describes the enforcement guideline, the evidence of growing national concern over DDT content in fish, and portions of the statutory scheme which could have been invoked by the raw chub distributors to establish tolerances for DDT residues in

legal significance of an "interim guideline" announced in a press release on April 22, 1969, as well as the district court's findings that the testing methods used by the government's experts were not sufficiently reliable to demonstrate that Vita's smoked chubs contained more DDT than the guideline permits.

A total ban on the future use of DDT would not resolve the problem presented by this case. Although the levels of DDT contamination are declining, we must assume that the chemical, or its derivatives, will survive as an ingredient of all or most foods for some time.[5]

Scientists seem to agree that if the DDT level is high enough, the food should not be consumed by man and, conversely, if the amount is sufficiently small, ingestion of DDT may be harmless. Danger levels have not been precisely defined. The record demonstrates, however, that in fish levels in the range of 5 parts per million are neither (a) generally recognized among qualified experts as safe,[6] nor (b) demonstrably injurious to health or unfit for human consumption.[7] At the levels disclosed by the record before us, the effect on human health is somewhat uncertain.

[1] Unquestionably DDT is a "pesticide chemical" as that term is defined in § 201(q) of F.D.C.A. See 21 U.S.C. § 321(q). Pursuant to statutory procedures, tolerances have been established for its use in or on various raw agricultural commodities, including fruits, etables, and meat.[8] Such foods therefore contain DDT within the scribed tolerance limits without "adulterated." It does not follow, ever, that a level which is either unsafe for one food would be safe or unsafe for another food.[9] respect to the foods for which DDT erances have been set, it is reasonable infer that the rule-making process have been invoked either by the FDA self, by manufacturers or distributors the pesticide, or by farmers or produ who are interested in using DDT pesticide. Fishermen, however, never had any interest in using or ing DDT themselves; its presence in environment is a condition of their —and also of the business of distrib ing or processing fish—for which are not responsible and which they no interest whatsoever in perpetuati In short, unlike farmers and pestici salesmen, they have never had any in est in adding DDT to the environm or to the food supply. From their p of view, it is not an item which is to their products; it is a natural comp nent of the fish before it is caught alone processed.

In this case the government's cla that defendants' chubs are "adulterate is not predicated on a claim that t particular fish defendants sell contai poisonous substance or are otherwise fit for food pursuant to either subpara graph (1) or subparagraph (3) of §

their products. The only contention raised by Ewig Bros. on this appeal is that Judge Gordon erroneously held that DDT residues in smoked chubs are a "food additive."

5. Concentration levels vary in different kinds of tissue. It is higher in Great Lakes fish than in most other foods, and especially high in the fat tissue and in fish caught in certain parts of Lake Michigan.

6. See also United States v. Goodman, *supra*, 486 F.2d 851–853.

7. The government made no effort to establish adulteration as defined in subparagraphs (a)(1) or (n)(3) of § 402. See 21 U.S.C. § 342.

8. See 40 C.F.R. § 180.147. Thus, for example, a tolerance of seven parts per mil has been established for a number of items including "fat of meat from cattle, goa hogs, horses, and sheep . . . spinach squash, ..." and a tolerance of only one part per million for a number of other items, such as artichokes, peanuts and radishes. Tolerances have also been established for dieldrin. 40 C.F.R. § 180.137.

9. Different foods are, of course, consumed in differing quantities and absorbed into the body under differing conditions. The elimination of fat by consuming only fillet of the fish, for example, may significantly reduce the intake of DDT.

of the F.D.C.A.[10] Under those subparagraphs the government would have the burden of proving that the fish are actually harmful to man. Instead, the government's claim is predicated on § 342(a)(2)(C),[11] under which it need only prove that "such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use . . . ." § 201(s) of the F.D.C.A., 21 U.S.C. § 321(s).[12]

It is the government's position that a fair analysis of the statutory scheme Congress has enacted, including the allocation of decision-making responsibility between the agency and the judiciary, justifies proceeding under this section. For if, as the government contends, DDT is a food additive, the Food and Drug Administration may itself decide when products containing quantities of DDT should be removed from public consumption, without having to rely upon the decisions—possibly inconsistent with one another—of different federal judges determining danger to health under §§ (a)(1) and (a)(3) on a case-by-case basis.

The question, then, is whether DDT and dieldrin in defendants' processed fish are "food additives" within the meaning of § 201(s).

I.

We have recently identified the principal purposes of the food additive amendment of 1958.[13] Neither the purpose to establish a procedure for premarketing clearance of untested food additives, nor the intent to permit the evaluation of such products to encompass a consideration of their benefits, as well as their potential for harm, seems directly relevant to the question before us. Rather, we are concerned with products which, at least primarily, were intended to be regulated as pesticide chemicals rather than as food additives. It is therefore appropriate to review the development of the pesticide chemical legislation enacted in 1954 as well as the food additive amendment itself.

Prior to 1938 a poisonous substance added to a food during processing would not cause adulteration unless the government could prove that the food itself, as

10. Sections 402(a)(1) and 402(a)(3), codified in 21 U.S.C. § 342, provide:

> A food shall be deemed to be adulterated —(a) Poisonous, insanitary, etc., ingredients.
>
> (1) 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;
>
> * * * * *
>
> (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

11. That section, also codified in 21 U.S.C. § 342, provides that a food shall be deemed adulterated

> (C) if it is, or if it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *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 346a of this title 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 346 and 348 of this title, 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 . . . .

Subsection (a)(2)(B) provides a similar standard:

> (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title . . . .

12. The government clearly met that burden in this case.

13. See Contineatal Chemiste Corp. v. Ruckelshaus, 7 Cir., 461 F.2d 331, 340–341 (1972).

opposed to the added substance, was unsafe.[14] After 1938, however, the statute has focused attention on the character of the added substance. Section 406 of the 1938 Act prohibited the use of poisonous or deleterious substances unless industry demonstrated that the substance was required for processing and also persuaded the Administrator[15] to issue a tolerance regulation permitting use in amounts below a specified level. Pending the promulgation of such a tolerance regulation, the addition of any poisonous or deleterious substance—even traces which could not possibly affect the safe character of the end product—constituted adulteration as a matter of law.[16] The "per se" approach adopted in 1938 placed the burden of proving safety upon industry and, as a matter of procedure, mandated marketing delays until after formal administrative review could be completed.

Although the 1938 Act authorized the promulgation of regulations limiting the amount of pesticide residues that remain in or on food (since such chemicals were obviously "poisonous or deleterious"), only one such regulation was actually issued during the subsequent 15-year period. The absence of such formal tolerance regulations was attributable, in part, to the expense and complexity of the rule-making procedure and, in part, to the required showing that use of the added substance be essential or unavoidable during processing.[17] Instead of employing the statutory procedure, the F.D.A. exercised practical control by means of an extra-legal system of unofficial and informal tolerances.[18]

The pesticide chemical amendment of 1954 was adopted to enable industry to make effective use of these poisonous products, even when not absolutely necessary, and to simplify, expedite, and improve the tolerance rule-making procedure[19]—as well as to remove uncertainty from the law.[20]

14. United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 34 S.Ct. 337, 58 L.Ed. 658.

15. See n. 3, *supra*.

16. To soften the impact of a rule which appeared to establish that food containing even traces of a deleterious substance was adulterated as a matter of law, some courts read the *de minimis* qualification which had existed under the previous statute, United States v. 133 Cases of Tomato Paste, 22 F.Supp. 515 (E.D.Pa.1938), into the new statute. See 338 Cartons, More or Less, of Butter v. United States, 165 F.2d 728 (4th Cir. 1947). See also United States v. 484 Bags, More or Less, 423 F.2d 839, 841 n. 1 (5th Cir. 1970).

17. The procedure before the 1954 amendments was described in the Senate Report as follows:

> Under existing law, added poisonous and deleterious substances—and most pesticide chemicals fall in this class—must be kept out of foods unless they are required in production or cannot be avoided by good manufacturing practice. When such a substance is required in production—as many pesticide chemicals are required in growing agricultural crops—a tolerance may be established by the Secretary of Health, Education, and Welfare, but only after a formal public hearing. Detailed findings of fact and conclusions must be made by the Secretary as to the required use of the pesticide and the residue levels that may safely be tolerated.

Sen.Rep.No.1635, 83rd Cong., 2d Sess., 2 U.S.Code Cong. & Admin.News 1954, p. 2627.

18. This system was apparently authorized by § 306 of the 1938 Act, codified as 21 U.S.C. § 336, which provides:

> Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

Some of the difficulties with this system are canvassed in Judge Frank's dissenting opinion in United States v. 449 Cases, Containing Tomato Paste, 212 F.2d 567, 575–581 (2d Cir. 1954).

19. The primary purpose of the bill is to assure greater protection of the public health by improving, simplifying, and speeding up the procedure under the Federal Food, Drug, and Cosmetic Act, for regulating the amount of residue which may remain on raw agricultural commodities after use of pesticide chemicals.

* * * * *

20. See Note 20 on page 721.

The 1954 Act created a category of added poisonous substances known as "pesticide chemicals" and authorized their use in or on "raw agricultural commodities" unless they were "unsafe" within the meaning of a newly enacted § 408.[21] That section provided that every pesticide chemical was "unsafe" unless exempted by the Secretary or used within a tolerance limit prescribed by the Secretary. Except insofar as courts would continue to read a *de minimis* exception into the new requirements,[22] and except insofar as the Administrator would decline to prosecute minor violations, every pesticide chemical was unsafe and caused adulteration unless and until it was the subject of a tolerance and thereafter used in conformity with the tolerance. As a matter of practice, a large number of tolerances were promulgated; the use of DDT and dieldrin was thereafter lawful as long as residues of these pesticides on raw agricultural commodities did not exceed specified limits.[23]

Just as the pesticide chemical amendment in 1954 created a new category of added substances which automatically caused adulteration unless exempted or used in conformity with an established tolerance, so did the 1958 amendment create still another new category—food additives—which also, by definition, caused adulteration unless exempted or used within a prescribed tolerance. Section 402, describing adulterated food, was amended to include any food which bears or contains an "unsafe" food additive, and every such additive was deemed unsafe unless used in compliance with a tolerance regulation issued under a new § 409.

Thus, congressional efforts to define and regulate adulterated food in the 20 years before 1958 reflected a consistent desire to rationalize the law by reducing the circumstances in which the F.D.A. must prove actual danger to a quantity of food and by establishing a system of tolerances which will both protect the public and enable industry to operate effectively.

The legislative history of the 1958 Bill indicates concern about the difficulties present when dangerous substances could not be proscribed by per se rules.[24] Since Congress used broad language in order to eliminate such difficulties, we should not construe it narrowly. The

A primary objective in drafting the bill was to develop legislation that would provide for prompt administrative action to permit effective use of pesticide chemicals without hazard to the public health; legislation that would be safe for consumers and practical for producers.

Sen.Rep.No.1635, 83rd Cong., 2d Sess., *supra* n. 17, at p. 2627.

20. . . . [C]ontrol . . . exercised through unofficial and informal tolerances . . . [, since] the necessary tolerances have not yet been issued . . . has been responsible for uncertainty under the law. It has handicapped the Government in enforcing the law, the grower in complying with the law, and the pesticide manufacturer and Federal and State agencies in discharging their responsibility for advising and making recommendations to the grower with respect to the use of pesticide chemicals.

Sen.Rep. No. 1635, 93rd Cong., 2d Sess., *supra* n. 17 at p. 2627.

21. This section is codified as 21 U.S.C. § 346a.

22. See n. 16, *supra*. We have found no case applying or refusing to apply the *de minimis* exception to products containing pesticide chemicals.

23. See n. 8, *supra*.

24. . . . [U]nder existing law the Federal Government is unable to prevent the use in foods of a poisonous or deleterious substance until it first proves that the additive is poisonous or deleterious. To establish this proof through experimentation with generations of mice or other animals may require 2 years or even more on the part of the relatively few scientists the Food and Drug Administration is able to assign to a particular problem. Yet, until that proof is forthcoming, an unscrupulous processor of foodstuffs is perfectly free to purvey to millions of our people foodstuffs containing additives which may or may not be capable of producing illness, debility, or death.

Sen.Rep.No.2422, 85th Cong., 2d Sess., 3 U.S.Code Cong. & Admin.News 1958, p. 5300.

language, set forth in full above,[25] defines a food additive as *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 . . . ." Although Congress was primarily concerned with substances used by a food processor, neither the language nor the history of the 1958 Act limits its application to such substances.[26] The words "the intended use of which" are not confined, as they easily could have been confined, to use in food processing.

Vita has argued that a process, such as smoking, during which nothing new is added to a food, cannot "transmogrify" a preexisting component of a food into an additive. But whether the food be fish, fruit, or meat, if the component is a pesticide chemical, we think that is exactly what Congress intended.

[2] Although it may seem odd to place the label "additive" on a chemical substance which was a component of the raw product and which is not changed by processing, Congress' choice of that label does not result in any "transmogrification." Before processing, DDT is a "pesticide chemical" on a raw product; after processing, it is an "additive." Since there is no tolerance for DDT on fish, both before and after processing the presence of the DDT causes fish to be adulterated without any proof that it is actually unfit as food. Defendants' contention, if accepted, would result in the anomaly that a chemical such as DDT would adulterate all raw fish, but adulteration of processed fish would be determined on an uncertain case-by-case basis. We conclude that such a construction of the statute is illogical and unacceptable.[27]

This conclusion is confirmed by the full text of the description of products which are "unsafe"—and therefore "adulterated"—because they contain food additives. Subsection (a)(2)(C) of § 402 provides that a food is adulterated:

> ". . . 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*;". 72 Stat. 1784. (Emphasis added.)

Quite clearly the need for the proviso arose from the fact that the definition of a "food additive" is broad enough to include any residue of a pesticide chemical remaining in or on food after proc-

25. See n. 1, *supra*.

26. See the passage from the Legislative History of the Act, quoted in n. 28, *infra*. Note the use of the words "principal examples" in the language which has been emphasized by Vita Foods.

27. . . . [T]his court is acutely aware of the fact that it is not the proper body to more narrowly define broad standards in this area so that they can be applied in a particular case. Courts know neither what is necessary for the health of the consuming public nor what can reasonably be expected from the canning industry. Furthermore, this is not a determination that should be made individually for each case on the basis of expert testimony. The Food and Drug Administration should set definite standards in each industry which, if reasonable, and in line with expressed Congressional intent, would have the force of law.
United States v. 1,500 Cases More or Less, Tomato Paste, 236 F.2d 208, 211 (7th Cir. 1956).

essing. Prior to the 1958 amendment only raw agricultural commodities could be adulterated as a matter of law because of the presence of such an added chemical; processed foods were not subject to that risk. Accordingly, prior to 1958, the exemption for such pesticide chemicals used within tolerance limits on raw agricultural commodities was sufficient to avoid the risk of "per se" adulteration for all food subject to that risk. But when the "per se" concept was enlarged to encompass processed food, which might, of course, contain some chemical residue, it became necessary either (a) to make the "food additive" and the "pesticide chemical" categories mutually exclusive, or else (b) to enact a specific proviso to cover the area of overlap. Congress made the latter choice.

The proviso which Congress enacted avoids the necessity for duplicate tolerances, one covering the use of the chemical on the raw commodity and the second applying to the same chemical after processing. The fact that an express proviso was needed to avoid that consequence confirms our reading of the food additive definition as broad enough to encompass pesticide chemical residues in processed food.

[3] Thus, the tolerances for DDT and dieldrin in or on raw fruits, vegetables, and meat are adequate to avoid adulteration caused by the residues remaining after the foods are processed. Without such tolerances, we think it is clear that the presence of DDT in or on such foods will cause adulteration pursuant to subparagraph (a)(2)(B) in their raw state, and that the same consequence will follow from subparagraph (a)(2)(C) after processing. We are also persuaded that these chemicals have the same impact on fish in the Great Lakes. As long as no tolerances have been established, the raw chubs are adulterated within the meaning of (a)(2)(B) because they contain an unsafe pesticide chemical; after processing, by virtue of (a)(2)(C), the chubs are adulterated because they contain an unsafe food additive. We think this is evident from the entire statutory scheme, the definitional language, and the relevant legislative history.[28] We

28. Thus, for example, consider the excerpt from the Senate Report:

Legislative History

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term "food additive" as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

Sen.Rep.No.2422, 85th Cong., 2d Sess., *supra* n. 24, at p. 5304.

hold, therefore, that the DDT and dieldrin found in defendants' smoked chubs were "food additives" and, since not protected by any tolerance, the chubs were "adulterated" as a matter of law.

II.

Vita Food argues, in the alternative, that even if DDT and dieldrin are food additives, we should nevertheless affirm because the government failed to prove that residues of these chemicals exceeded the limits specified in the F.D.A. interim enforcement guidelines. In its opinion the district court stated that there is never "perfect certainty" in any scientific analysis and that the government's test methods were "not sufficiently reliable for me to find by the greater weight of the evidence and as a controlling fact that the chubs sampled by FDA in April 1972 contained DDT concentration in excess of 5 ppm." 356 F.Supp. 1213, 1221.[29]

Neither party has contested the applicability of the F.D.A.'s 5 ppm enforcement guideline. Nevertheless, it is clear that the government might have argued that the enforcement guideline was merely adopted as an internal standard to determine when it would be appropriate to initiate an enforcement proceeding, and that publication in a Press Release was merely intended to give industry fair notice of its internal standards. By way of analogy, a police department might adopt a policy of not enforcing a 55 mile speed limit unless a motorist's speed exceeded 65 miles per hour. Under such a policy, at a trial it would not be necessary to prove anything more than a speed in excess of 55. By comparison, the F.D.A. might as a matter of discretion withhold enforcement unless it found residues of over 5 ppm, but have no legal obligation to prove anything more than a trace to establish statutory adulteration.[30]

[4] We do not so interpret the interim guidelines before us in this case; for both the language of the Press Release[31] and the government's treat-

29. It is not clear whether it is completely accurate to characterize these observations in the district court's opinion as findings of fact. Since the court had held that DDT is not a food additive, the government could not prevail unless it proved that the quantity of DDT in Vita's smoked chubs made them unfit for food or injurious to health. Clearly, the government did not sustain that burden. Under the district court's view of the law, which we have rejected, its observations about the unreliability of the government's test methods and about the sufficiency of the evidence proving excessive residues of DDT were unnecessary to its decision. On the other hand, its finding "that the test method to be used by processors of smoked chub is not sufficiently precise for a finding of fact that the chubs sampled in April 1972 contained DDT concentrations in excess of 5 ppm," 356 F.Supp. at 1221, can fairly be termed an alternative ground for granting judgment for the defendants. For if DDT in processed food was not a food additive under § 321(s), and if the government failed to prove it a known health hazard, a conclusion that the preponderance of the evidence did not sustain a conclusion that defendants' fish exceeded 5 ppm would have been unnecessary. If such a finding is in fact an alternative ground for decision, it must be sustained unless it is clearly erroneous. Rule 52(a), Fed.R.Civ.P.

30. This appears to be F.D.A.'s position with respect to its 0.5 ppm guideline for mercury in swordfish, since it has contended that that guideline is without legal significance. See Hearings on the Effects of Mercury on Man and the Environment Before the Subcomm. on Energy, Natural Resources, and the Environment of the Senate Comm. on Commerce, 91st Cong., 2d Sess., pt. 1, at 36, cited in Note, Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish, 85 Harv.L.Rev. 1025, 1028–1029 (1972).

31. The 1969 Press Release stated in part:

> The interim limit of 5 ppm for DDT residues will apply to all fish marketed interstate. Pesticide monitoring by FDA, however, indicates that DDT residues are below 1 ppm in 90 percent of the fish marketed in this country.
>
> Tolerances for DDT residues in other foods vary from product to product. The tolerance is .05 ppm for milk and 7 ppm for a wide variety of fruits and vegetables and in the fat of meat. FDA has taken steps to reduce a number of these where experience has shown that lower levels are practicable. App. 123.

ment of it in this case [32] indicates that it was meant to operate more like a rule of general applicability than a mere prediction of how the agency would choose to exercise its prosecutorial discretion.[33] Accordingly, even though the government was not obligated to adopt any interim guideline, and might have let industry accept the responsibility for initiating tolerance proceedings, it correctly assumed the burden of proving that appellant violated the specified limits.[34]

[5] The district court considered the AOAC method of testing for chemical residues insufficiently precise for the government to sustain its burden. It is clear, however, that the enforcement guidelines must have been adopted on the assumption—shared by government and industry—that existing methods of testing DDT were sufficiently accurate to permit meaningful administration of the limits specified therein. The AOAC method was used by both the government technicians and by the expert employed by appellant. However imprecise that method may be, the record indicates that it is the best method that can be used. Certainly the government must be permitted to use the best testing method yet devised by analytical chemists, for the enforcement guidelines must have been predicated upon that method. Therefore, without disagreeing with the district court's observation that the AOAC method falls short of perfect certainty, we cannot accept the view that it may not be used to evaluate appellants' compliance with the guidelines. The district court's contrary determination was clearly erroneous.

[6] Acceptance of the AOAC method as the proper standard for measuring residues of pesticide chemicals in fish leads inexorably to the conclusion that the government met its burden of proving repeated violations of the guidelines. In July and August of 1969, and again in the fall of 1969, the F.D.A. collected and analyzed smoked chubs shipped by Vita in interstate commerce and found quantities of DDT and its derivatives ranging from 5.97 ppm to 9.67 ppm. Tr. 663–665. After this case had been commenced, additional samples were analyzed and found to contain 5.37 to 9.28 ppm.[35] These samples were subsequent-

The 0.3 ppm enforcement guideline for dieldrin has been in existence for more than 20 years. App. 62. The Record discloses no reason why its legal significance is different from that for DDT.

32. The government engaged in a protracted evidentiary hearing for the purpose of establishing that Vita's fish contained DDT in excess of 5 ppm, without ever contending, so far as we can determine from the record, that such proceedings were unnecessary.

33. The Press Release contains no language similar to that found in the "Merger Guidelines" released by the Department of Justice to inform the business community of its enforcement policy for Section 7 of the Clayton Act: "[T]hese guidelines are announced solely as a statement of current Department policy, subject to change at any time without prior notice . . . ." Department of Justice "Merger Guidelines," p. 1. See United States v. Atlantic Richfield Co., 297 F.Supp. 1061, 1073 (S.D.N.Y.1969).

34. *Cf.* Nixon v. United States, —— U.S. ——, 94 S.Ct. 3090, 41 L.Ed.2d 1039 (1974); Vitarelli v. Seaton, 359 U.S. 535, 539, 79 S.Ct. 968, 3 L.Ed.2d 1012; United States ex rel. Accardi v. Shaughnessy, 347 U.S. 260, 74 S.Ct. 499, 98 L.Ed. 681; United States v. Heffner, 420 F.2d 809 (4th Cir. 1970). We do not suggest that there is anything to prevent the F.D.A. from changing the guideline it has enunciated, or even from enforcing the statute Congress has enacted with no guideline at all. Although there are objections to enforcement in this way, see Judge Frank's dissenting opinion in United States v. 449 Cases Containing Tomato Paste, *supra* n. 18, the industry would clearly have a remedy in the statutory procedure for the establishment of tolerances. 21 U.S.C. § 348. We hold only that, for purposes of this litigation, the Enforcement Guideline is binding upon F.D.A., notwithstanding the informal manner of its release, as if it were a general rule published in accord with the requirements of the Administrative Procedure Act.

35. A check test, run by a second chemist, yielded a range from 6.06 ppm to 9.88 ppm. See Defendants' Ex. 15.

ly analyzed by an expert employed by appellant; he found that three out of the seven samples contained DDT in excess of 5 ppm and that the other ranged from 3.89 to 4.37. Finally, in October of 1972, samples were sent to Seattle for analysis with results ranging from 5.42 ppm to 6.54 ppm. Tr. 623.

Whether we accept the government's evidence at face value—and since we have held that the AOAC procedure is acceptable, and since the detailed records supporting the government's conclusion are in the record, there is persuasive reason to do so—whether we assume that the truth lies somewhere in between the views of the respective litigants' experts, or even if we take the defendants' evidence, it is perfectly clear that the limit specified in the 1969 guidelines has been violated. A shipper of processed food may violate the statute even if some, or even a majority, of its food is not adulterated. The evidence is uncontradicted that the Act as implemented by the guideline, has been violated.

Vita argues, however, that there really is no significant difference between DDT levels of 5 ppm and levels as high as 8 ppm. But that is an argument that should not be addressed to us; it may properly be asserted as a reason for setting a tolerance at 8 ppm or perhaps even higher. The F.D.A. need not have set its guideline limit at 5 ppm, but it did so, and industry has not seen fit to invoke the statutory procedures for establishing a different tolerance level. In these circumstances, the government has met its burden by proving that the guidelines have been exceeded repeatedly.

The judgment in United States v. Vita Foods is therefore reversed and remanded for the entry of appropriate relief. In view of the nature of the case and the trial judge's familiarity with the technical materials in the record, Circuit Rule 23 shall not apply.

The judgment in United States v. Ewig Bros. Co. is affirmed.

UNITED STATES of America, Appellee,
v.
Fred H. WATTS, Appellant.
No. 73-3141.

United States Court of Appeals, Ninth Circuit.

Sept. 5, 1974.

Defendant was convicted in the United States District Court for the Southern District of California, Leland C. Nielsen, J., of conspiring to bribe public officials, bribery, and giving false testimony before a grand jury, and he appealed. The Court of Appeals, Ely, Circuit Judge, held that Court would not entertain challenge to sufficiency of evidence, that admission of defendant's grand jury testimony was proper, and that denial of defendant's request for grand jury testimony of named witness was harmless error.

Affirmed.

1. Criminal Law ⇐1044.1(7)

Court of Appeals would not entertain challenge to sufficiency of evidence supporting perjury convictions, where there was no motion for judgment of acquittal in trial court and there was no manifest miscarriage of justice to warrant review of evidence notwithstanding lack of motion.

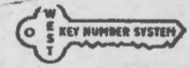
2. Perjury ⇐32(1)

Grand jury witness who was advised of his constitutional rights on each occasion that he was called to testify, who was fully advised of nature of investigation and acknowledged that he understood nature of investigation before he presented grand jury testimony was clearly given full extent of his constitutional rights; thus, his grand jury testimony was admissible in perjury prosecution.

special favor to those who have misappropriated their rent allowance. If there were no recoupment provision, there would be a disincentive for welfare recipients to manage their grants so as to have funds available to pay their rent each month. The recoupment provision encourages proper money management, an entirely acceptable, if incidental, purpose of the welfare legislation.

No doubt there are other ways in hich the state could accomplish the ends ved by the use of the recoupment reg- ion. However it is not for us to ate the wisdom of the state's choice ans. If these means are rationally to a proper end, as they are in , we have no power to go fur-

no substantial constitutional resented, the district court risdiction to consider the urged by plaintiffs. We this case with instruc- want of jurisdiction.



H & H TIRE COMPANY, Petitioner,

v.

UNITED STATES DEPARTMENT OF TRANSPORTATION et al., Respondents.

No. 71-1935.

United States Court of Appeals, Seventh Circuit.

Argued April 5, 1972.

Decided Dec. 5, 1972.

Action by an independent tire retreader seeking judicial review of a federal motor vehicle safety standard issued by Department of Transportation pursuant to the National Traffic and Motor Vehicle Safety Act of 1966. The Court of Appeals, Pell, Circuit Judge, held that where safety administration, in promulgating standard which established specified processing and performance requirements for retreaded pneumatic passenger tires and which incorporated five laboratory performance tests that were part of safety standard for new tires, including high speed and endurance tests, failed to inquire adequately into certain important topics, including practicability of standard, thereby slighting statutorily required considerations, and, further, failed to evaluate reasonably the relevant, available data, standard, insofar as it incorporated high speed and endurance tests, must be set aside.

Set aside in part.

Stevens, Circuit Judge, concurred and filed opinion.

1. Administrative Law and Procedure ⇐390

Fact that a government regulation may cause economic hardship to a party does not make such regulation unreasonable.

2. Automobiles ⇐10

Where safety administration, in promulgating standard which established specified processing and performance requirements for retreaded pneumatic passenger tires and which incorporated five laboratory performance tests that were part of safety standard for new tires, including high speed and endurance tests, failed to inquire adequately into certain important topics, including practicability of standard, thereby slighting statutorily required considerations, and, further, failed to evaluate reasonably the relevant, available data, standard, insofar as it incorporated high speed and endurance tests, must be set aside. National Traffic and Motor Vehicle Safety Act of 1966, § 1 et seq., 15 U.S.C.A. § 1381 et seq.

3. Administrative Law and Procedure ⇐816

When an administrative decision is made without consideration of relevant factors, it must be set aside.

Good "regulatory reform" concurrence

Hammond E. Chaffetz, Fred H. Bartlit, Jr., and Tefft W. Smith, Kirkland & Ellis, etc., Chicago, Ill., for petitioner.

Alan S. Rosenthal, Thomas J. Press, Lawrence G. Schneider, Frank Berndt, Michael P. Peskoe, Attys., Dept. of Justice, Washington, D. C., for respondents.

Before PELL, STEVENS, and SPRECHER, Circuit Judges.

PELL, Circuit Judge.

Petitioner H & H Tire Company, an independent tire retreader, seeks judicial review of Federal Motor Vehicle Safety Standard No. 117 (Standard 117) [1] issued by the Department of Transportation pursuant to the National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1381 et seq. Standard 117 establishes specified processing and performance requirements for retreaded pneumatic passenger tires.[2] On petitioner's motion, this court, pending its review, stayed the enforcement of the standard, scheduled to have become effective January 1, 1972.

The purpose of the 1966 Safety Act is "to reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents," 15 U.S.C. § 1381. Toward that end, Congress conferred upon the Secretary of the Department of Transportation the power to establish federal motor vehicle safety standards,[3] which are defined as "minimum standard[s] for motor vehicle performance, or motor vehicle equipment performance . . .," 15 U.S.C. § 1391(2). The Secretary in turn delegated this authority to respondent National Highway Traffic Safety Administration (Safety Administration). The Act requires compliance with the Administrative Procedure Act (the A.P.A.), 5 U.S.C. § 501 et seq.

When it was engaged in informal rulemaking procedures, 5 U.S.C. § 553, that resulted in the issuance of Standard 117, the Safety Administration received comments reflecting a difference of opinion about the kind of rule the Administration should adopt. Some interested parties preferred a performance standard which would test the performance of completed retreaded tires regardless of their method of manufacture. Others advocated a processing standard setting forth approved methods and processes by which tires should be retreaded. Those favoring performance standards maintained that retreaded tires could and should be expected to meet the same performance standards established for new tires. Standard 117 in its final form reflects this point of view and incorporates five laboratory performance tests that are part of the safety standard for new tires, Standard 109.[4]

In December 1971, after the Safety Administration failed to amend Standard 117 so as to obviate their objections to the inclusion of two of Standard 109's performance tests, H & H Tire Company, several other independent retreaders, and the American Retreaders' Association, Inc. instituted suit in the District Court for the Northern District of Illi-

1. 36 F.R. 7315 (April 17, 1971) (formal issuance). See also 32 F.R. 14278 (October 14, 1967) and 35 F.R. 4136 (March 5, 1970). For amendments unrelated to the petitioner's challenge here, see 36 F.R. 20877 (Oct. 30, 1971), 36 F.R. 22239 (Nov. 23, 1971) and 36 F.R. 24814 (Dec. 23, 1971).

2. Retreading involves the fusion, through vulcanization, of a new tread into a tire casing from which the prior tread has been worn through use. The manufacture of retreaded tires, an industry over fifty years old, accounts for approximately one of every four tires produced in the United States, or about fifty million tires annually. There are some 8500 retreaders, most of whom are small, independent operators.

3. "The Secretary shall establish by order appropriate Federal motor vehicle safety standards. Each such Federal motor vehicle safety standard shall be practicable, shall meet the need for motor vehicle safety, and shall be stated in objective terms."
15 U.S.C. § 1392(a).

4. 36 F.R. 22914 (Dec. 2, 1971). See also 36 F.R. 23067 (Dec. 3, 1971).

nois to have Standard 117 declared invalid and its enforcement enjoined. A week later, the plaintiffs voluntarily dismissed the action, and H & H Tire Company filed the present petition for review.[5]

Petitioner here urges that Standard 117 must be set aside because it allegedly is in excess of statutory authority and was fashioned without observance of the procedures required by law. Petitioner's attack on the substantive validity of the standard centers on its incorporation of Standard 109's "high speed" and "endurance" tests, which were developed originally for new tires.[6] The issuance of Standard 117 was allegedly procedurally improper because the Safety Administration failed to provide the "concise general statement of [the standard's] basis and purpose" required by Section 4 of the A.P.A., 5 U.S.C. § 553.

I

The scope of our review is prescribed by Section 10 of the A.P.A., now 5 U.S.C. §§ 701–706.

"When the issue on appeal is whether a rule made in informal proceedings [under A.P.A. § 4, 5 U.S.C. § 553] meets the criteria of Section 10, the court must necessarily go about the application of that standard in a manner unlike its review of findings of fact and conclusions of law compiled in a formal proceeding [A.P.A. §§ 7, 8, 5 U.S.C. §§ 556, 557].

"This exercise need be no less searching and strict in its weighing of whether the agency has performed in accordance with the Congressional purposes. . . . The paramount objective is to see whether the agency, given an essentially legislative task to perform, has carried it out in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future." Automotive Parts & Accessories Ass'n, Inc. v. Boyd, 132 U.S.App.D.C. 200, 407 F.2d 330, 338 (1968).

If the requirements of Section 10 have not been satisfied, we must "hold unlawful and set aside [the] agency action. . . ." A.P.A. § 10(e), 5 U.S.C. § 706.[7]

5. The Safety Act, 15 U.S.C. § 1394(a), provides for direct review of federal motor vehicle safety standards by U. S. courts of appeals.

6. The two challenged laboratory performance tests are adopted in § 5.1.1(e) and § 5.1.1(f) of Standard 117. The tests run tires under stress on a 67-inch smooth steel laboratory wheel. In the high speed performance test, the tire is first run for a two hour break-in period at 50 m. p. h., then for ½ hour at 75 m. p. h., then ½ hour at 80 m. p. h., and finally for ½ hour at 85 m. p. h. At the conclusion of the test, the tire is not permitted to show signs of tread, ply, or bead separation, chunking, or broken cords. According to the Government, this test is designed to measure the tire's ability to perform at high temperatures. In the endurance test, a tire runs on the laboratory wheel for 34 continuous hours at a set rate of 50 m. p. h., with a weight load that is periodically increased until it is the equivalent of a 33% overload. This test is allegedly designed to gauge the ability of the tire to withstand loads for extended periods of time.

The other three tests that Standard 117 takes from Standard 109 are static tests measuring resistance to the unseating of the tire from the tire rim ("bead unseating" test), tire cord body strength ("breaking energy" test), and tire size.

7. 5 U.S.C. § 706 provides in part:

"To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action.

The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) *arbitrary, capricious, an abuse of discretion,* or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) *in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;*

The Safety Act provides that a proposed standard is to be "practicable," to "meet the need for motor vehicle safety," [8] to be based upon the consideration of relevant, available motor vehicle safety data,[9] and to be "reasonable, practicable and appropriate" for the particular item of motor vehicle equipment regulated, 15 U.S.C. §§ 1392, 1395. Petitioner H & H Tire contends that Standard 117 satisfies none of these mandatory criteria for a proposed motor vehicle safety regulation.

The House debate on its proposed safety bill suggests that by "practicable" the legislators meant that all relevant factors be considered by the agency, "including technological ability to achieve the goal of a particular standard as well as consideration of economic factors." 112 Cong.Rec. 19648 (Aug. 17, 1966). The Report of the Senate Commerce Committee recommending passage of the Senate's version of the safety act, which was the basis for the version ultimately enacted, stated: "The committee recognizes . . . that the Secretary will necessarily consider [in the issuance of standards] reasonableness of cost, feasibility and adequate lead time." 2 U.S. Code Cong. & Adm.News, 89th Cong., 2d Sess., 1966, p. 2714.

Petitioner refers us to evidence in the record [10] that production retread tires

(D) without observance of procedure required by law;

. . . . .

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error." [Emphasis added.]

8. The Act, defines "Motor vehicle safety" as follows:

". . . the performance of motor vehicles or motor vehicle equipment in such a manner that the public is protected against unreasonable risk of accidents occurring as a result of the design, construction or performance of motor vehicles and is also protected against unreasonable risk of death or injury to persons in the event accidents do occur, and includes nonoperational safety of such vehicles."

15 U.S.C. § 1391(1).

9. The Act requires the Safety Administration to "conduct research, testing, development, and training necessary to carry out the purposes of this subchapter. . . . ." Among the activities authorized are:

"(1) collecting data from any source for the purpose of determining the relationship between motor vehicle or motor vehicle equipment performance characteristics and (A) accidents involving motor vehicles, and (B) the occurrence of death, or personal injury resulting from such accidents;

"(2) procuring . . . experimental and other motor vehicles or motor vehicle equipment for research and testing purposes. . . ."

15 U.S.C. § 1395(a)(1) and (2).

10. Before the briefs were filed, the petitioner moved this court to allow the administrative record to be supplemented by twelve additional exhibits: four are depositions of Safety Administration officials taken pursuant to the dismissed district court proceedings, two are public statements by the agency, and the rest consist mainly of affidavits embodying sworn statements of fact that the petitioner states were previously submitted to the Safety Administration in informal form. As this court ordered, the parties devoted part of their briefs to the propriety of including these additional materials.

Respondents concede that the additional material is, to a large extent, an elaboration of evidence previously submitted to the Safety Administration. To the extent that "new evidence" is involved, they contend that 15 U.S.C. § 1394(a)(2) controls. That section authorizes the court of appeals to remand a case to the agency for its consideration of new evidence where the petitioner has shown reasonable grounds for its failure to adduce the new evidence before the agency.

We have included the additional material in our review of the evidence in this case. We do not agree with respondents that the exhibits merely "encumber the record." Further, and this is particularly true of the depositions of officials of the Safety Administration, the material is not "new" in the sense of being unknown to the agency. To remand the case for consideration of these few exhibits at this juncture would create even further delay in the disposition of the controversy.

cannot comply with Standard 117. With one significant exception, tests by the tire industry revealed substantial rates of failure for retreads on the endurance and the high speed tests. The combined failure rates were 28% on the endurance test and 17% on the high speed test. Only the Tire Retreading Institute, a division of the National Tire Dealers and Retreaders Association, Inc., found that 100% of the tires it tested passed. As petitioner points out, however, the record does not establish whether the few tires tested by the Institute were randomly selected production retreads or were new tire casings simply buffed and retreaded. Although tests conducted by the Safety Administration apparently had varying results, the failure rates there were also not insignificant.

The Government points out that some retreaders have admitted they might be able to redesign their tires so that they would be more likely to pass the high speed and endurance laboratory tests.[11] We cannot agree that these statements prove that Standard 117 satisfies Congress's intent that a safety standard be both technologically and economically feasible. The respondents refer us to no analyses of the costs of such design changes nor to determinations of how long it would take the retreading industry to begin production of the redesigned retreads.

Standard 117 and the statute under which it was promulgated require every producer of retreaded tires to certify that each retreaded passenger tire it manufactures to sell or introduce into interstate commerce conforms to the standard. The Safety Act provides for a civil penalty of up to $1000 for each separate violation and a maximum penalty of $400,000 for any related series of violations. 15 U.S.C. §§ 1397, 1398. In light of the not negligible failure rate of retreads as presently designed on the two challenged tests and the possibility that the industry's best efforts might be insufficient to insure prompt compliance with Standard 117, the penalties established by the Act might have a considerable economic impact on the retreading industry.

[1] These considerations, taken alone, do not conclusively establish that the issuance of Standard 117 violates Section 10 of the A.P.A. We agree with the Government that "the fact that a government regulation may cause economic hardship to a party does not make such regulation unreasonable." The deleterious economic effect on the industry of required compliance with Standard 117 might be permissible if retreads unquestionably were major safety hazards and if compliance with the standard clearly enhanced retreads' safety under on-the-road conditions. However, it appears to be a fair statement from the record that, except for excessive wear (bald or thin tires), tires in general, retreaded tires included, pose no significant safety problem.[12] Also, we have some doubts whether Standard 117 meets the need for motor vehicle safety as required by the authorizing statute. The purpose of the regulation was to provide the public with retreaded passenger car tires capable of performing safely under modern driving conditions,

11. We note that analyses in the record by some retreaders suggest that the redesigning of retreads to increase the likelihood of their passing the Standard 109 tests might not eliminate all failures. Petitioner alleges that a significant percentage of retreads would still fail the tests. And, according to at least one tire expert, a Firestone Tire & Rubber Company engineer, the design changes necessary to improve laboratory performance may degrade rather than promote the safety of retreads in actual highway use.

12. Cf. In the Senate Report accompanying the bill ultimately passed, the Commerce Committee declared: "The Secretary is not expected to issue a standard covering every component and function of a motor vehicle, but only for those vehicle characteristics that have a significant bearing on safety." 2 U.S.Code Cong. & Adm.News, 89th Cong., 2d Sess. 1966, p. 2714.

35 F.R. 4136, 36 F.R. 7315. The respondents can cite little evidence in the administrative record in support of their assertion that the challenged tests are appropriate to predict the safety of retreads in road performance—that is, "correlation"—and, thus, to achieve the valid goal announced by the Safety Administration. Indeed, studies by the Administration itself suggest the need for further research on the degree to which Standard 109's tests correlate with road testing results.

Thus, we cannot conclude from the record before us that the respondents adequately investigated the practicability of Standard 117 before issuing it. Rather, it appears that the Safety Administration minimized the importance of a close inquiry into the costs to the retreaders that Standard 117 would entail. It thereby adopted a rule which, if implemented now, might possibly destroy a well-established industry. The agency acted precipitately, without adequate study.

Furthermore, the respondents seem to overlook the fact that, if economic analyses were to show that retreaders would suffer severe economic hardship, either by being forced out of business or by being priced out of their market, the retreaders' customers would also suffer. As the Safety Administration stated in its March 5, 1970 notice of proposed rulemaking, "There is a large segment of the motoring public that relies on retreaded tires for use on passenger cars." 35 F.R. 4136. In their responses to the notice, some retreaders stated that purchasers of retreads are often persons who cannot afford new tires or who, because of the expense of new tires, continue to use worn out tires much longer than they, in safety, should. The Safety Act explicitly recognizes that tires may be new or retreaded, *e. g.*, 15 U.S.C. § 1402(g), § 1421(1). This certainly militates against the idea that Congress intended to authorize the respondents to narrow the selection or alternatives available to consumers when they decide to buy automobile tires.

We also agree with the analysis contained in Judge Stevens's concurring opinion.

II

As we analyze the respondents' position, its underlying structure is that the Safety Administration, pursuant to Congressional permission, utilized informal rulemaking procedures rather than the more formal adjudicatory processes and because the standard promulgated related to safety it was virtually unchallengeable. The availability of informal rulemaking procedures is not equatable with administrative fiat. There must be some assurance discernible that the administrative action was reasoned and based on a consideration of relevant factors. Nor is the action to be saved by the importance of the subject. We do not minimize the desirability of all reasonable and practicable steps for the diminution of highway carnage. That, of course, could be accomplished by the elimination of all privately owned automobiles. We do not understand that Congress had that in mind. Meeting the "need for motor vehicle safety" may be accomplished with much less and still be "reasonable, practicable and appropriate."

[2, 3] From our examination and analysis of the record, we hold that the Safety Administration, when promulgating Standard 117, failed to inquire adequately into certain important topics, thereby slighting statutorily-required considerations, and, further, failed to evaluate reasonably the relevant, available data. *Cf.* Shannon v. United States Dept. of Housing & Urban Dev., 436 F. 2d 809, 819 (3d Cir. 1970), "When an administrative decision is made without consideration of relevant factors it must be set aside"; Scenic Hudson Preservation Conference v. Federal Power Commission, 354 F.2d 608, 612, 620 (2d Cir. 1965), "The Commission has an affirmative duty to inquire into and consider all relevant facts." Hence, Standard 117 as presently formulated does not meet the Safety Act's requirements for safety

standards, particularly subsections 1392(a), 1392(f)(1), (3), and (4). As a spokesman for The Firestone Tire & Rubber Company, a major new tire firm that also produces retreads, noted, the respondents have failed to "demonstrat[e] that . . . [Standard] 117 is necessary, or even useful, to effectuate the purposes of the Act of 1966."

Because of our decision concerning the substantive invalidity of Standard 117, we do not address ourselves to petitioner's argument that the requirements of Section 4 of the A.P.A., 5 U.S.C. § 553, were not satisfied.

Insofar as Standard 117 incorporates the high speed and endurance tests of Standard 109, we set aside the order establishing the standard issued by the Department of Transportation, acting through the National Highway Traffic Safety Administration. The case is remanded for further proceedings not inconsistent with this opinion.

Set aside in part.

STEVENS, Circuit Judge (concurring).

As they are used, tires become less safe. Anyone who elects to drive at an excessive speed or on tires that have already traveled thousands of miles over a variety of road surfaces assumes some risk of tire failure. For that reason, at some point in time most car owners make a choice among four alternatives: (1) to continue driving on the old tires they then own; (2) to replace them with somewhat better used tires; (3) to replace them with retreads; or (4) to replace them with new tires.

Respondent has determined that the third alternative may not be selected unless the retread will last as long and perform just as well as a new tire. If that determination is enforced, the cost of retreads will increase and inevitably some car owners will reject the third alternative. Some will prolong their use of old tires; some will replace worn tires with others that are only slightly better; and the most cautious will pay the price of a new set of tires which may have a longer life expectancy than the used vehicle on which they will be placed. Thus, among the predictable effects of the enforcement of Standard 117 are the following: (1) some people will be driving on less safe tires; (2) some people will buy more expensive tires than they really need; and (3) since fewer retreads will be sold, new tire manufacturers will have less vigorous competition to face. In short, there is a cost to society at large associated with the enforcement of Standard 117.

On the other hand, it is no doubt true that the sale of defective retreads, or the sale of retreads that will not perform as long or as well as drivers anticipate, may pose a significant safety hazard. My problem with this case stems from the fact that there is nothing in the record to indicate that respondent assessed the magnitude of that potential hazard, or considered whether measures specifically mentioned in the statute, such as fair labeling, tire quality grading,[1] and limits on the age of tire carcasses which can be retreaded,[2] would sufficiently protect the consumer without curtailing his choice among apparently acceptable alternatives.[3]

Although I recognize that safety is the "overriding consideration in the issuance of standards" under this Act,[4] the statute requires respondent to consider whether a proposed standard is "reasonable, practicable and appropriate" before it is prescribed.[5] In my opinion this duty has not been discharged until respondent has at least identified some of the costs associated

1. 15 U.S.C. § 1423.

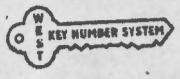
2. 15 U.S.C. § 1426.

3. A reading of the entire Subchapter II ("Tire Safety"), 15 U.S.C. §§ 1421–1426, plainly indicates that Congress contemplated that retreads would remain a viable consumer choice.

4. Senate Rep.No.1301, 89th Cong., 2d Sess. 6 (1966), p. 2714.

5. 15 U.S.C. § 1392(f)(3).

with the proposal and determined that these costs are overridden by reasonably predictable benefits. Since no such consideration is evidenced by this record, I agree that respondent failed to perform his statutory duty.



MIDCONTINENT BROADCASTING COMPANY, a corporation, Appellant,

v.

NORTH CENTRAL AIRLINES, INC., Appellee.

No. 72-1307.

United States Court of Appeals, Eighth Circuit.

Submitted Nov. 14, 1972.

Decided Jan. 17, 1973.

In action seeking to recover lost profits for destruction of television tower which was struck by aircraft, the United States District Court for the District of Minnesota, William J. Lindberg, Senior District Judge, granted defendant's motion for judgment n. o. v. and, in the alternative, its motion for new trial, and plaintiff appealed. The Court of Appeals, Lay, Circuit Judge, held that grounds that the trial court erred in admission of certain evidence and that plaintiff failed to conform to the best available evidence rule were not appropriate to motion for judgment n. o. v.; rather, they were proper considerations in granting motion for new trial.

Judgment set aside and case remanded for new trial.

1. Federal Civil Procedure ⇐2603

Ground that trial court erred in its admission of certain evidence was not appropriate in connection with motion for judgment n. o. v.; rather, it was a proper consideration in granting motion for new trial.

2. Federal Civil Procedure ⇐2608

In ruling on the sufficiency of evidence, the trial court must take the record as presented to the jury and cannot enter judgment n. o. v. on a record altered by the elimination of incompetent evidence.

3. Federal Civil Procedure ⇐2334

The proper remedy to correct any evidentiary error, whether it involves direct or collateral issues, is new trial.

4. Federal Civil Procedure ⇐2334

For new trial to be granted on ground of evidentiary error, the error must have been prejudicial, and this necessarily implies failure of proof which goes to the very heart of the case.

5. Evidence ⇐177

Generally, an expert witness may testify to and summarily state the net result of having examined voluminous books and records, but it is generally required that the mass of records be placed at the hand of the court or at least made accessible to the opposing party.

6. Federal Civil Procedure ⇐2603

Assuming plaintiff failed to conform to the best available evidence rule, such failure was purely evidentiary in nature and its legal effect was appropriate only when motion for new trial, not for judgment n. o. v., was under consideration.

7. Federal Civil Procedure ⇐2334

It was peculiarly within the competence of the trial court to grant a new trial on basis of evidentiary rulings, and holding that the trial court did not abuse its discretion in doing so did not necessarily place a stamp of imprimatur on the trial court's evidential rulings.

Harding A. Orren, Minneapolis, Minn., for appellant.

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