

United States Court of Appeals,
Fifth Circuit.
UNITED STATES of America, Plaintiff,
v.
ANDERSON SEAFOODS, INC. et al., Defendants.
ANDERSON SEAFOODS, INC. et al., Plaintiffs-Appellants,
v.
Patricia Roberts HARRIS, Secretary of Health and Human Services et al.,
Defendants-Appellees.
No. 78-1962.
July 24, 1980.

Enforcement action instituted by the United States with respect to distribution of swordfish was consolidated with class action by distributors for declaratory and injunctive relief. The United States District Court for the Northern District of Florida, at Mariana, Winston E. Arnow, Chief Judge, [447 F.Supp. 1151](#), entered a judgment from which distributor appealed. The Court of Appeals, Wisdom, Circuit Judge, held that: (1) the term "added," as used in provision of the Food, Drug, and Cosmetic Act defining adulterated foods, means artificially introduced, or attributable in some degree to the acts of man; (2) where some portion of a toxin present in a food has been introduced by man, the entirety of that substance present in the food will be treated as an "added substance" and so considered under the "may render injurious to health" standard of the Food, Drug, and Cosmetic Act; and (3) there was sufficient evidence to show that some mercury in swordfish is attributable to the acts of man. Affirmed.

West Headnotes

 [\[1\] KeyCite Notes](#)

 [178](#) Food
 [178k5](#) k. Purity and Quality. [Most Cited Cases](#)

If a substance is deemed "added," then the Food and Drug Administration need only show that it "may render [the food] injurious to health" in order to regulate consumption of the food containing the substance; the "may render" standard means that there is a reasonable possibility of injury to the consumer; however, if a substance is considered "not-added," the FDA must go further and show that the substance would "ordinarily render [the food] injurious to health" before it can regulate its consumption. Federal Food, Drug, and Cosmetic Act, § 402(a)(1), [21 U.S.C.A. § 342\(a\)\(1\)](#).

 [\[2\] KeyCite Notes](#)

 [178](#) Food
 [178k5](#) k. Purity and Quality. [Most Cited Cases](#)

Term "added," as used in provision of the Food, Drug, and Cosmetic Act defining adulterated foods, means artificially introduced, or attributable in some degree to the acts of man. Federal Food, Drug, and Cosmetic Act, § 402(a)(1), [21 U.S.C.A. §](#)

[342\(a\)\(1\)](#).

[\[3\] KeyCite Notes](#)

[178](#) Food

[178k5](#) k. Purity and Quality. [Most Cited Cases](#)

Where some portion of a toxin present in a food has been introduced by man, the entirety of that substance present in the food will be treated as an "added substance" and so considered under the "may render injurious to health" standard of the Food, Drug, and Cosmetic Act. Federal Food, Drug, and Cosmetic Act, § 402(a)(1), [21 U.S.C.A. § 342\(a\)\(1\)](#).

[\[4\] KeyCite Notes](#)

[178](#) Food

[178k5](#) k. Purity and Quality. [Most Cited Cases](#)

Food, Drug, and Cosmetic Act's "may render injurious to health" standard was triggered by evidence that some mercury in swordfish is attributable to the acts of man--that mercury is dumped into rivers and washed onto the continental shelf where some of it is methylated by bacteria and taken up by plankton, and that it thereby enters the food chain of swordfish. Federal Food, Drug, and Cosmetic Act, § 402(a)(1), [21 U.S.C.A. § 342\(a\)\(1\)](#).

***158** Eric M. Blumberg, Stephen D. Terman, Food and Drug Adm., Rockville, Md., Robert Wiggers, John J. Powers, III, App. Section, Antitrust Div., Dept. of Justice, Washington, D. C., for Patricia Roberts Harris. Robert T. Lasky, Susan A. Elliott, Washington, D. C., for plaintiffs-appellants. Appeal from the United States District Court for the Northern District of Florida.

Before WISDOM, POLITZ and SAM D. JOHNSON, Circuit Judges.

WISDOM, Circuit Judge:

This appeal poses the question whether mercury in the tissues of swordfish is an "added substance" within the meaning of the Food, Drug, and Cosmetic Act, [21 U.S.C. s 342\(a\)\(1\) \(1975\)](#) (FDA), and is, therefore, subject to regulation under the relaxed standard appropriate to added substances. Only part of that mercury has been added by man.

In April 1977, the United States sought an injunction against Anderson Seafoods, Inc., and its president, Charles F. Anderson, to prevent them from selling swordfish containing more than 0.5 parts per million (ppm) of mercury, which it considered adulterated under the meaning of [s 342\(a\)\(1\)](#) of the FDA. Anderson responded in May 1977 by seeking a declaratory judgment that fish containing 2.0 ppm of mercury or less are not adulterated. Anderson also sought an injunction against the Food and Drug Administration commensurate with the declaratory judgment. Anderson's suit was certified as a class action, and these suits were consolidated for trial.

The district court denied the injunction that the government sought. In Anderson's suit, the court also denied an injunction, but issued a declaratory judgment that ***159** swordfish containing more than 1.0 ppm mercury is adulterated under [s 342\(a\)\(1\)](#). In doing so, the court determined that mercury is an "added substance" under the Act and rejected Anderson's contention that a level of 2.0 ppm is acceptable. Anderson appealed from the judgment in the class action. The government appealed from the judgment in

its enforcement action and cross-appealed in the class action. The government then withdrew its appeal and cross-appeal. This appeal now consists of Anderson's challenge to the way the district court parsed the statute and to the sufficiency of the evidence. We affirm.

I.

[Section 342\(a\)\(1\)](#) of the Act provides:

A food shall be deemed to be adulterated (a)(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.

[21 U.S.C. s 342\(a\)\(1\)](#).

[1] The Act does not define "added substance". Whether a substance is added or not is important because of the evidentiary showing that the Food and Drug Administration must make to succeed in an enforcement action. If a substance is deemed "added", then the Agency need show only that it "may render (the food) injurious to health" in order to regulate consumption of the food containing the substance. The "may render" standard has been interpreted to mean that there is a reasonable possibility of injury to the consumer. See [United States v. Lexington Mill & Elevator Co., 1914, 232 U.S. 399, 34 S.Ct. 337, 58 L.Ed. 658](#); [Berger v. United States, 8 Cir. 1952, 200 F.2d 818, 821](#). If, however, a substance is considered "not-added", the Agency must go further, and show that the substance would "ordinarily render (the food) injurious to health", [21 U.S.C. s 342\(a\)\(1\)](#), before it can regulate its consumption. In the trial of this case three theories about the meaning of the term "added" emerged. The Food and Drug Administration sponsored the first theory. It argues that an "added substance" is one that is not "inherent". According to FDA regulations:

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

[21 C.F.R. ss 109.3\(c\), \(d\) \(1977\)](#). Under this theory, all the mercury in swordfish is an added substance, because it results not from the creature's bodily processes but from mercury in the environment, whether natural or introduced by man.

Anderson put forward a second theory. A substance, under this theory, is not an added substance unless it is proved to be present as a result of the direct agency of man. Further, only that amount of a substance the lineage of which can be so traced is "added". If some mercury in swordfish occurs naturally, and some is the result of man-made pollution, only that percentage of the mercury in fish proved to result directly from pollution is an added substance.

The district court adopted a third theory. Under the court's theory, if a de minimis amount of the mercury in swordfish is shown to result from industrial pollution, then all of the metal in the fish is treated as an added substance and may be regulated under the statute's "may render injurious" standard. The legislative history and case law, though sparse, persuade us that this is the proper reading of the statute.

***160** The distinction between added and not-added substances comes from the "adulterated food" provisions of the original Food, Drug, and Cosmetic Act of 1906, ch. 3915, 34 Stat. 768. The legislative history shows that "added" meant attributable to acts of man, and "not-added" meant attributable to events of nature. See H.R.Rep.No. 2118, 59th Cong., 1st Sess. 6, 7, 11 (1906) (quoted in [United States v. Coca Cola, 1915, 241 U.S. 265, 282-83, 36 S.Ct. 573, 578- 79, 60 L.Ed. 995](#) ("deleterious

substances added by man"); 40 Cong.Rec. 1133 (Jan. 16, 1906) ("human action") (remarks by Sen. Heyburn). That the distinction was carried through to the present Act is shown by its legislative history. S.Rep.No. 493, 73rd Cong., 2d Sess. 3 (1934) ("added by man or put there by nature . . . introduced by artifice or (occurring) naturally").

The Supreme Court drew the same distinction in [United States v. Coca Cola, 1915, 241 U.S. 265, 36 S.Ct. 573, 60 L.Ed. 995](#). Construing the "added . . . ingredient" provisions of the 1906 Act, the Court said:

Congress, we think, referred to ingredients artificially introduced; these are described as 'added.' The addition might be made to a natural food product or to a compound . . . we think that it was the intention of Congress that the artificial introduction of ingredients of a poisonous or deleterious character which might render the article injurious to health should cause the prohibition of the statute to attach.
[241 U.S. at 284, 36 S.Ct. at 579.](#)

[2] The Food and Drug Administration argues that there need not be any connection between man's acts and the presence of a contaminant for it to be considered an added substance. The Agency points to the rule it recently promulgated interpreting [s 342\(a\)\(1\)](#), quoted above, which defines an added substance as one which is not "an inherent natural constituent of the food", but is instead the "result of an environmental, agricultural, industrial, or other contamination". [21 C.F.R. ss 109.3\(c\), \(d\) \(1977\)](#). Under the rule, mercury in swordfish tissue deriving from the mercury naturally dissolved in sea water would be an added substance, as would any substance not produced by or essential for the life processes of the food organism. In light of the legislative history and the Coca Cola case, however, we agree with the district court that the term "added" as used in [s 342\(a\)\(1\)](#) means artificially introduced, or attributable in some degree to the acts of man. [447 F.Supp. 1151, 1155](#). The Food and Drug Administration finds further support for its view in several cases in which the courts refer to not-added substances under the Act as "inherent". In [Continental Chemiste Corp. v. Ruckelshaus, 9 Cir. 1972, 461 F.2d 331, 337](#), and [Certified Color Ind. Committee v. Secretary of HEW, 2 Cir. 1956, 236 F.2d 866, 869](#), however, the courts were not defining the statutory term "added substance". That they referred to not-added substances as being inherent does not mean that all non-inherent substances are added. These cases are consistent with the proposition that some non-inherent substances, present in a food organism but unconnected to man's acts, are not-added substances under the Act. A final case, [United States v. An Article of Food Consisting of Cartons of Swordfish, S.D.N.Y., 1975, 395 F.Supp. 1184](#), reads the Act to mean that any material obtained from the environment is an added substance. As the district court pointed out, "FDA has not urged this rather extreme position upon the court and the ruling, contrary to the legislative history of the Act and the language of the Supreme Court, is not persuasive authority." [447 F.Supp. at 1155](#). Determining that man must appear on the stage before a substance is an added one does not determine the size of the role he must play before it is. The dichotomy in [s 342\(a\)\(1\)](#) is between two clear cases that bracket the present case. The Act considers added things such as lead in coloring agents or caffeine in Coca Cola. It considers not-added things like oxalic acid in rhubarb or caffeine in coffee. The Act did not contemplate, however, the perhaps rare problem of a toxin, part of which occurs ***161** "naturally", and part of which results from human acts. The section is designed, of course, to insure the scrutiny of toxins introduced by man. As Senator Heyburn said of the 1906 Act:

Suppose you would say if there is poison in (a food) already it cannot do much harm to put in more. Suppose commercial cupidity should tempt someone to add to the dormant poison that is in a hundred things that we consume everyday, are they to be permitted to do it? This bill says they shall not do it.
40 Cong.Rec. 2758 (1906).

Anderson argues that when a toxin derives in part from man and in part from nature, only that part for which man is responsible may be considered added and so regulated under the "may render injurious" standard. In such a case, however, neither the statute nor FDA regulations suggest that the amount of an added toxic substance be quantified and shown to have a toxic effect of its own if the total amount of the substance in a food is sufficient to render the food potentially hazardous to health. It may be possible as in this case to prove that man introduced some percentage of a toxin into a food organism, but difficult or impossible to prove that percentage.

Since the purpose of the "may render injurious" standard was to facilitate regulation of food adulterated by acts of man, we think that it should apply to all of a toxic substance present in a food when any of that substance is shown to have been introduced by man. Anderson argues that this reading of the statute would result "in the anomalous situation where a substance in a food can be 90 percent natural and 10 percent added if the entire substance is considered as added". There is no anomaly, however, in such a situation. The Act's "may render it injurious to health" standard is to be applied to the food, not to the added substance. The food would not be considered adulterated under our view unless the 10 percent increment creates or increases a potentiality of injury to health. If the increment does create or increase such a potentiality, then, because the increment that triggered the potentiality was introduced by man, the Food and Drug Administration ought to be able to regulate it under the standard designed to apply to adulterations of food caused by man. Anderson's argument proves too much. Anderson would argue that if a swordfish contained 0.99 ppm of natural mercury, and 0.99 ppm of mercury from human sources, the fish could be sold although it contained nearly twice as much mercury as the district court found to be a safe level. Such a reading of the statute hardly accords with its "overriding purpose to protect the public health". [United States v. Bacto-Unidisk, 1969, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726.](#) The reading we have adopted does accord with this purpose. It may be severe in practice. It may permit the Food and Drug Administration to regulate in some cases where the amount of substance contributed by man which triggers the potentiality of harm is minute. But it is the only alternative that fits into the statutory scheme. Congress should amend the statute if our reading produces impracticable results. [\[FN1\]](#)

[FN1.](#) For a review of the policy arguments favoring less regulation, see [Note, Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish, 85 Harv.L.Rev. 1025 \(1972\).](#)

[\[3\]](#)  In sum, we hold that where some portion of a toxin present in a food has been introduced by man, the entirety of that substance present in the food will be treated as an added substance and so considered under the "may render injurious to health" standard of the Act.

II.

In addition to its attack on the way the district court parsed the statute, Anderson raises a subsidiary argument. There was insufficient evidence to support the conclusion that man's acts contributed "substantial amounts" of mercury to the tissues of swordfish. And, indeed, the court did not find that the amounts were substantial, but rather that they were unknown and perhaps *162 unquantifiable. Under our reading of the statute, however, the amount of mercury that man contributes need not be "substantial". The FDA need show only that some portion of the mercury is attributable to acts of man, and that the total amount may be injurious to health.

[4] There was sufficient evidence to show that some mercury is attributable to the acts of man. There was evidence that mercury is dumped into rivers and washes onto the continental shelf, where some of it is methylated by bacteria and taken up by plankton. It thereby enters the food chain of swordfish, for the plankton is consumed by small organisms and fish, such as copepods, herring, and hake, which are in turn eaten by larger organisms, and eventually by swordfish, a peak predator. This evidence was enough to trigger the Act's "may render injurious to health" standard.

III.

The district court set 1.0 ppm as the health limit for mercury in swordfish. It noted that the decision was:

based only on the scientific and empirical data accepted into evidence in these cases. It may be that further studies will reveal the decisions here made were based on erroneous or insufficient data.

[447 F.Supp. at 1160](#). We noted above that the government withdrew its appeal and cross-appeal. It is apparently considering new evidence to determine whether its present action level should be reaffirmed or changed. Our decision does not engrave the district court's 1.0 ppm level in administrative stone. While the government may not now prevent the sale of swordfish containing 1.0 ppm or less of mercury, the durability of our order is founded on the evidence the district court accepted.

The order of the district court is AFFIRMED.

C.A.Fla., 1980.

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622 F.2d 157

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