United States Court of Appeals,
District of Columbia Circuit.
PUBLIC CITIZEN, et al., Petitioners,
v.
Dr. Frank **YOUNG**, Commissioner, Food and Drug Administration, et al.,
Respondents.
Cosmetic, Toiletry and Fragrance Association, Intervenor.
PUBLIC CITIZEN, et al., Appellants,
v.
DEPARTMENT OF HEALTH & HUMAN SERVICES, et al.
Nos. 86-1548, 86-5150.

Argued March 26, 1987.
Decided Oct. 23, 1987.

Suits were brought challenging decision of Food and Drug Administration to list two color additives as safe, and FDA's "provisional" listing of ten other color additives. The United States District Court for the District of Columbia, Stanley S. Harris, J., entered judgment, and appeal was taken. The Court of Appeals, Williams, Circuit Judge, held that: (1) Color Additive Amendments' Delaney Clause, which prohibits Food and Drug Administration from listing as safe any color additive "found * * * to induce cancer in man or animal," does not contain an implicit de minimis exception for carcinogenic dyes with trivial risks to humans, and (2) Food and Drug Administration could postpone expiration of color additives' provisional listings where it found that postponements for further evaluation were consistent with public health, that evaluations were going forward in good faith, that they would be completed as soon as reasonably practicable, and none had been found to induce cancer in humans or animals.

Ordered accordingly.

West Headnotes

[1] Food 5
178k5 Most Cited Cases
Color Additive Amendments' Delaney Clause, which prohibits Food and Drug Administration from listing as safe any color additive "found * * * to induce cancer in man or animal," does not contain an implicit de minimis exception for carcinogenic dyes with trivial risks to humans. Federal Food, Drug, and Cosmetic Act, §§ 706, 706(b)(5)(B), as amended, 21 U.S.C.A. §§ 376, 376(b)(5)(B).

[2] Food 5
178k5 Most Cited Cases
Food and Drug Administration could postpone expiration of color additives' provisional listings where it found that postponements for further evaluation were consistent with public health, that evaluations were going forward in good faith, that they would be completed as soon as reasonably practicable, and none had been found to induce cancer in humans or animals. Federal Food, Drug, and Cosmetic Act, §§ 706, 706(b)(5)(B), as amended, 21 U.S.C.A. §§ 376, 376(b)(5)(B).

***1109 **350** Appeal from the United States District Court for the District of Columbia (Civil Action No. 85-00209).

William B. Schultz, with whom Katherine A. Meyer and Alan B. Morrison were on the brief for petitioners in No. 86-1548 and appellants in No. 86-5150.

Douglas N. Letter, Appellant Litigation Counsel, Dept. of Justice, with whom Richard K. Willard, Asst. Atty. Gen., Robert L. Cynkar, Deputy Asst. Atty. Gen., Margaret A. Cotter, Asst. Director, Jacqueline H. Eagle, Attorney, Dept. of Justice, Thomas Scarlett, Chief Counsel and Richard E. Geyer, Associate Chief Counsel, Food and Drug Admin. were on the brief for respondents in No. 86-1548.

Robert C. Seldon, Asst. U.S. Atty., with whom Joseph E. diGenova, U.S. Atty., Royce C. Lamberth, R. Craig Lawrence, Asst. U.S. Attys.,

Thomas Scarlett, Chief Counsel and Richard E. Geyer, Associate Chief Counsel, Food and Drug Admin. were on the brief for federal appellees in No. 86-5150.

John P. McKenna, with whom Daniel R. Thompson was on the brief for appellee, Certified Color Mfrs. Ass'n in No. 86-5150.

Peter Barton Hutt for intervenor in No. 86-1548. Robert M. Sussman, Ellen J. Flannery, and Bruce N. Kuhlik were on the brief for the Cosmetic, Toiletry and Fragrance Ass'n appellee in No. 86-5150 and intervenor in No. 86-1548.

Before RUTH B. GINSBURG and WILLIAMS, Circuit Judges, and HAROLD H. GREENE, [FN*] District Judge.

FN* Of the United States District Court for the District of Columbia, sitting by designation pursuant to 28 U.S.C. § 292(a).

Petition for Review of an Order of the Food and Drug Administration

Opinion for the Court filed by Circuit Judge WILLIAMS.

WILLIAMS, Circuit Judge:

The Color Additive Amendments of 1960, Pub.L. No. 86-618, 74 Stat. 397 (codified at 21 U.S.C. § 376 (1982)), part of the Food, Drug and Cosmetic Act (the "Act"), establish an elaborate system for regulation of color additives in the interests of safety. A color additive may be used only after the Food and Drug Administration ("FDA") has published a regulation listing the additive for such uses as are safe. Such listing may occur only if the color additive in question satisfies (among other things) the requirements of the applicable "Delaney Clause," § 706(b)(5)(B) of the Act, 21 U.S.C. § 376(b)(5)(B), one of three such clauses in the total system for regulation of color additives, food and animal food and drugs. [FN1] The Clause prohibits the listing of any color additive "found ... to induce cancer in man or animal."

FN1. The other clauses relate to food additives, 21 U.S.C. § 348(c)(3)(A), and to animal drugs, *id.* § 306b(d)(1)(H). All clauses prohibit carcinogens. The clauses differ slightly in language, more materially in statutory context and legislative history.

In No. 86-1548, Public Citizen and certain individuals challenge the decision of the FDA to list two color additives, Orange No. 17 and Red No. 19, based on quantitative risk assessments indicating that the cancer risks presented by these dyes were trivial. This case thus requires us to determine whether the Delaney Clause for color additives is subject to an implicit "*de minimis* " exception. We conclude, with some reluctance, that the Clause lacks such an exception.

In a second case argued the same day, No. 86-5150, Public Citizen and others challenged the FDA's persistence in giving "provisional" listing to ten color additives, including several found to cause cancer in laboratory animals. The agency has since removed most of the colors at issue from ***1110 **351** the provisional list, mooting the case as to these colors. At present, only three of the original colors, Red Nos. 3, 33 and 36, are still provisionally listed. Apart from those rendered moot, we find that these claims are either foreclosed by circuit law or unripe.

I. THE DELANEY CLAUSE AND "DE MINIMIS" EXCEPTIONS

A. *Factual Background*

The FDA listed Orange No. 17 and Red No. 19 for use in externally applied cosmetics on August 7, 1986. *See* 21 C.F.R. §§ 74.1267, 74.2267 (1987) (Orange No. 17); *id.* §§ 74.1319, 74.2319 (Red No. 19). In the listing notices, it carefully explained the testing processes for both dyes and praised the processes as "current state-of-the-art toxicological testing." 51 Fed.Reg. 28,331, 28,334 (Aug. 7, 1986) (Orange No. 17); *id.* at 28,346, 28,349 (Red No. 19). In both notices it specifically rejected industry arguments that the Delaney Clause did not apply because the tests were inappropriate for eval-

uation of the dyes. 51 Fed.Reg. at 28,342; *id.* at 28,358-59. It thus concluded that the studies established that the substances caused cancer in the test animals. *Id.* at 28,334-36, 28,341 (Orange No. 17 "induces cancer when tested in laboratory animals"); *id.* at 28,349-52, 28,357 (Red No. 19 "induces cancer when tested in laboratory animals").

The notices then went on to describe two quantitative risk assessments of the dyes, one by the Cosmetic, Toiletry and Fragrance Association ("CTFA," an intervenor here and the industry proponent of both dyes) and one by a special scientific review panel made up of Public Health Service scientists. Such assessments seek to define the extent of health effects of exposures to particular hazards. As described by the National Research Council, they generally involve four steps: (1) hazard identification, or the determination of whether a substance is causally linked to a health effect; (2) dose-response assessment, or determination of the relation between exposure levels and health effects; (3) exposure assessment, or determination of human exposure; and (4) risk characterization, or description of the nature and magnitude of the risk. *See* National Research Council, *Risk Assessment in the Federal Government: Managing the Process* 3 (National Academy Press 1983) ("*Risk Assessment*"). All agree that gaps exist in the available information and that the risk estimator must use assumptions to fill those gaps. *See, e.g., Report of the Color Additive Scientific Review Panel* (Sept. 1985), Joint Appendix ("J.A.") in No. 86-1548, at 139-40, 167. The choice among possible assumptions is inevitably a matter of policy to some degree. *See Risk Assessment* at 3. [FN2]

FN2. Agencies have used quantitative risk assessments in a variety of regulatory contexts. For example, the Occupational Safety and Health Administration is under a mandate to establish standards "reasonably necessary or appropriate to provide safe or healthful ... places of employment," 29 U.S.C. § 652(8) (1982), which was construed in *Industrial Union Dep't v. American Petroleum Institute,* 448 U.S. 607, 639-40, 100 S.Ct. 2844, 2862-63, 65 L.Ed.2d 1010 (1980), to call for promulgation of standards only where appropriate to remedy a "significant risk of material health impairment." In fulfillment of this mandate, OSHA used quantitative risk assessment in promulgating a rule on exposure limits to airborne inorganic arsenic. 48 Fed.Reg. 1864 (1983). *See also* Environmental Protection Agency, "Guidelines for Carcinogen Risk Assessment," 51 Fed.Reg. 33,992 (1986). The FDA itself has used the technique in evaluating safety where the Delaney Clause did not apply. *See* 47 Fed.Reg. 14,138 (1982) (Green No. 6). *See also* Cooper, *Stretching Delaney Till It Breaks,* Regulation 11 (Nov./Dec. 1985) (describing FDA's increasing confidence in quantitative risk assessment); Nichols and Zeckhauser, *The Perils of Prudence: How Conservative Risk Assessments Distort Regulation,* Regulation 13 (Nov./Dec. 1986) ("Quantitative risk assessment is an increasingly important tool in regulatory decisions involving health and safety."). FDA has also used the technique in the face of the Delaney Clause in approving a carcinogenic food additive, methylene chloride. 50 Fed. Reg. 51,551 (1985). A challenge to the methylene chloride determination is currently pending before this court. *Public Citizen v. Bowen,* No. 86-1494.

The assessments considered the risk to humans from the substances when used in various cosmetics--lipsticks, face powders and rouges, hair cosmetics, nail products, bathwater products, and wash-off products. ***1111 **352** The scientific review panel found the lifetime cancer risks of the substances extremely small: for Orange No. 17, it calculated them as one in 19 billion at worst, and for Red No. 19 one in nine million at worst. The FDA explained that the panel had used conservative assumptions in deriving these figures, and it characterized the risks as "so trivial as to be effectively no risk." It concluded that the two dyes were safe. 51

Fed.Reg. at 28,344, 28,360.

The FDA candidly acknowledged that its safety findings represented a departure from past agency practice: "In the past, because the data and information show that D & C Orange No. 17 is a carcinogen when ingested by laboratory animals, FDA in all likelihood would have terminated the provisional listing and denied CTFA's petition for the externally applied uses ... without any further discussion." *Id.* at 28,341; *accord id.* at 28,357 (same for Red No. 19). It also acknowledged that "[a] strictly literal application of the Delaney Clause would prohibit FDA from finding [both dyes] safe, and therefore, prohibit FDA from permanently listing [them]...." *Id.* at 28,341; *id.* at 28,356. Because the risks presented by these dyes were so small, however, the agency declared that it had "inherent authority" under the *de minimis* doctrine to list them for use in spite of this language. *Id.* at 28,341; *id.* at 28,358. It indicated that as a general matter any risk lower than a one-in-one-million lifetime risk would meet the requirements for a *de minimis* exception to the Delaney Clause. *Id.* at 28,344; *id.* at 28,362.

Assuming that the quantitative risk assessments are accurate, as we do for these purposes, it seems altogether correct to characterize these risks as trivial. For example, CTFA notes that a consumer would run a one-in-a-million lifetime risk of cancer if he or she ate *one* peanut with the FDA-permitted level of aflatoxins once every *250* days (liver cancer). *See* J.A. 529, citing FDA Bureau of Foods, *Assessment of Estimated Risk Resulting From Aflatoxins in Consumer Peanut Products and Other Food Commodities* (1978). Another activity posing a one-in-a-million lifetime risk is spending 1,000 minutes (less than 17 hours) every year in the city of Denver--with its high elevation and cosmic radiation levels--rather than in the District of Columbia. *See* J.A. 530. Most of us would not regard these as high-risk activities. Those who indulge in them can hardly be thought of as living dangerously. Indeed, they are risks taken without a second thought by persons whose economic position allows them a broad range of choice.

According to the risk assessments here, the riskier dye poses one ninth as much risk as the peanut or Colorado hypothetical; the less risky one poses only one 19,000th as much.

It may help put the one-in-a-million lifetime risk in perspective to compare it with a concedely dangerous activity, in which millions nonetheless engage, cigarette smoking. Each one-in-a-million risk amounts to less than one *200,000th* the lifetime risk incurred by the average male smoker. J.A. 536, citing E. Crouch & R. Wilson, "Inter-Risk Comparisons," in J. Rodricks & R. Tardiff, eds., *Assessment and Management of Chemical Risks* 97, 105, 108 (1984). Thus, a person would have to be exposed to more than 2,000 chemicals bearing the one-in-a-million lifetime risk, at the rates assumed in the risk assessment, in order to reach 100th the risk involved in smoking. To reach that level of risk with chemicals equivalent to the less risky dye (Orange No. 17), he would have to be exposed to more than 40 million such chemicals.

B. *Plain Language and the* de Minimis *Doctrine*

The Delaney Clause of the Color Additive Amendments provides as follows:

> a color additive ... (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the ***1112 **353** Secretary to induce cancer in man or animal.... [FN3]
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> FN3. This quotation omits subsection (i), which concerns uses involving ingestion; none of the uses here at issue concerns such a use.

21 U.S.C. § 376(b)(5)(B).

The natural--almost inescapable--reading of this language is that if the Secretary finds the additive to "induce" cancer in animals, he must deny listing. Here, of course, the agency made precisely

the finding that Orange No. 17 and Red No. 19 "induce[ ] cancer when tested in laboratory animals." (Below we address later agency pronouncements appearing to back away from these statements.)

The setting of the clause supports this strict reading. Adjacent to it is a section governing safety generally and directing the FDA to consider a variety of factors, including probable exposure, cumulative effects, and detection difficulties. 21 U.S.C. § 376(b)(5)(A). The contract in approach seems to us significant. For all safety hazards other than carcinogens, Congress made safety the issue, and authorized the agency to pursue a multifaceted inquiry in arriving at an evaluation. For carcinogens, however, it framed the issue in the simple form, "If A [finding that cancer is induced in man or animals], then B [no listing]." There is language inviting administrative discretion, but it relates only to the process leading to the finding of carcinogenicity: "appropriate" tests or "other relevant exposure," and the agency's "evaluation" of such data. Once the finding is made, the dye "shall be deemed unsafe, and shall not be listed." 21 U.S.C. § 367(b)(5)(B).

Courts (and agencies) are not, of course, helpless slaves to literalism. One escape hatch, invoked by the government and CTFA here, is the *de minimis* doctrine, shorthand for *de minimis non curat lex* ("the law does not concern itself with trifles"). The doctrine--articulated in recent times in a series of decisions by Judge Leventhal--serves a number of purposes. One is to spare agency resources for more important matters. *See Alabama Power Co. v. Costle,* 636 F.2d 323, 360 (D.C.Cir.1979). But that is a goal of dubious relevance here. The finding of trivial risk necessarily followed not only the elaborate animal testing, but also the quantitative risk assessment process itself; indeed, application of the doctrine required additional expenditure of agency resources.

More relevant is the concept that "notwithstanding the 'plain meaning' of a statute, a court must look beyond the words to the purpose of the act where its literal terms lead to 'absurd or futile results.' " *Alabama Power,* 636 F.2d at 360 n. 89 (quoting *United States v. American Trucking Ass'ns,* 310 U.S. 534, 543, 60 S.Ct. 1059, 1063, 84 L.Ed. 1345 (1939)). Imposition of pointless burdens on regulated entities is obviously to be avoided if possible, *see Alabama Power,* 636 F.2d at 360-61, especially as burdens on them almost invariably entail losses for their customers: here, obviously, loss of access to the colors made possible by a broad range of dyes.

We have employed the concept in construing the Clean Air Act's mandate to the Environmental Protection Agency to set standards providing "an ample margin of safety to protect the public health," 42 U.S.C. § 7412(b)(1) (1982). That does not, we said, require limits assuring a "risk-free" environment. Rather, the agency must decide "what risks are acceptable in the world in which we live" and set limits accordingly. *See Natural Resources Defense Council, Inc. v. EPA,* 824 F.2d 1146, 1164-65 (D.C.Cir.1987) (citing *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.,* 448 U.S. 607, 642, 100 S.Ct. 2844, 2864, 65 L.Ed.2d 1010 (1980). Assuming as always the validity of the risk assessments, we believe that the risks posed by the two dyes would have to be characterized as "acceptable." Accordingly, if the statute were to permit a *de minimis* exception, this would appear to be a case for its application. [FN4]

> FN4. We do not, of course, purport to decide the appropriate dividing point between *de minimis* and other risks. FDA's proposed one-in-one-million dividing point has been used by EPA to distinguish acceptable and unacceptable risks. 49 Fed.Reg. 46,294 (1984) (general guidelines); 51 Fed.Reg. 1602, 1635 (1986) (hazardous wastes). FDA has used the same break point to determine whether the general safety clause of the Act applies. 47 Fed.Reg. 14,138 (1982).

***1113 **354** Moreover, failure to employ a *de minimis* doctrine may lead to regulation that not only is "absurd or futile" in some general cost-benefit

sense but also is directly contrary to the *primary* legislative goal. *See id.* at 360 (*de minimis* doctrine a "tool to be used in implementing the legislative design"). In a certain sense, precisely that may be the effect here. The primary goal of the Act is human safety, but literal application of the Delaney Clause may in some instances increase risk. No one contends that the Color Additive Amendments impose a zero-risk standard for non-carcinogenic substances; if they did, the number of dyes passing muster might prove miniscule. As a result, makers of drugs and cosmetics who are barred from using a carcinogenic dye carrying a one-in-20-million lifetime risk may use instead a noncarcinogenic, but toxic, dye carrying, say, a one-in-10-million lifetime risk. The substitution appears to be a clear loss for safety.

Judge Leventhal articulated the standard for application of *de minimis* as virtually a presumption in its favor: "Unless Congress has been extraordinarily rigid, there is likely a basis for an implication of *de minimis* authority to provide [an] exemption when the burdens of regulation yield a gain of trivial or no value." *Alabama Power*, 636 F.2d at 360-61. But the doctrine obviously is not available to thwart a statutory command; it must be interpreted with a view to "implementing the legislative design." *Id.* at 360. Nor is an agency to apply it on a finding merely that regulatory costs exceed regulatory benefits. *Id.* at 361.

Here, we cannot find that exemption of exceedingly small (but measurable) risks tends to implement the legislative design of the color additive Delaney Clause. The language itself is rigid; the context--an alternative design admitting administrative discretion for all risks other than carcinogens--tends to confirm that rigidity. Below we consider first the legislative history; rather than offering any hint of softening, this only strengthens the inference. Second, we consider a number of factors that make Congress's apparent decision at least a comprehensible policy choice.

1. *Legislative History*

The Delaney Clause arose in the House bill and was, indeed, what principally distinguished the House from the Senate bill. The House included it in H.R. 7624, 106 Cong.Rec. 14,353-56, and the Senate accepted the language without debate, 106 Cong. Rec. 15,133 (1960). The House committee gave considerable attention to the degree of discretion permitted under the provision. The discussion points powerfully against any *de minimis* exception, and is not contradicted either by consideration on the House floor or by a post-enactment colloquy in the Senate.

House Committee. The House Report on the Color Additive Amendments is the most detailed evidence as to Congress's intentions on this issue. H.R.Rep. No. 1761, 86th Cong., 2d Sess. (1960), U.S.Code Cong. & Admin.News p. 2887 (hereinafter the "*House Report* "). In discussing the Clause, the report first explains the source of concern: "[T]oday cancer is second only to heart disease as a cause of death among the American people. Every year, approximately 250,000 people die of cancer in this country. Approximately 450,000 new cases of cancer are discovered each year." *Id.* at 11, U.S.Code Cong. & Admin.News 1960, p. 2893. The report reflects intense congressional concern over cancer risks from man-made substances. [FN5]

> FN5. For other indicia of congressional anxiety, *see infra* p. 1117 and nn. 11-12.

The report acknowledged the "many unknowns about cancer," but highlighted certain areas of general agreement: "Laboratory experiments have shown that a number of substances when added to the diet of test animals have produced cancers of various kinds in the test animals. It is this fact--namely, that small quantities of certain materials over a period of time will cause abnormal cell growth in animals--that gave rise to the Delaney anticancer clause...." *Id.* The report quoted at ***1114 **355** length from the hearing testimony of Arthur S. Flemming, Secretary of Health, Education, and Welfare (the parent agency of the FDA and the predecessor of Health and Human Services). The Sec-

retary took a very strong line on the absence of a basis for finding "threshold" levels below which carcinogens would not be dangerous:

> We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.

Id. at 13, U.S.Code Cong. & Admin.News 1960, p. 2894. [FN6]

> FN6. In fact the existence of a threshold for chemical carcinogens, below which their use would have no ill effect, appears to depend on whether one is speaking of an "initiating" agent, a "promoting" agent, or a "complete carcinogen." (The latter both initiates and promotes.) Both activities are necessary for the production of tumors. Both the theory of the operation of initiating agents and the empirical data support the belief that for them no threshold applies. Equally, the theory and data as to promoting agents support the view that there is a "no-effect" threshold level. *See* H. Pitot, "Principles of Cancer Biology: Chemical Carcinogenesis," 1 *Cancer: Principles and Practice of Oncology* 79-99 (V. DeVita, S. Hellman, & S. Rosenberg, 2d eds. 1985).

Secretary Flemming also developed the theme that, with many cancer risks inescapably present in the environment, it made sense to remove unnecessary ones:

> Unless and until there is a sound scientific basis for the establishment of tolerances for carcinogens, I believe the Government has a duty to make clear-- in law as well as in administrative policy--that it will do everything possible to put persons in a position where they will not unnecessarily be adding residues of carcinogens to their diet.
>
> The population is inadvertently exposed to certain carcinogens.... In view of these facts, it becomes all the more imperative to protect the public from deliberate introduction of additional carcinogenic materials into the human environment.
>
> * * *
>
> It is clear that if we include in our diet substances that induce cancer when included in the diet of test animals, we are taking a risk. In light of the rising number of cases of cancer, why should we take that risk?

Id. at 12-13, U.S.Code Cong. & Admin.News 1960, p. 2894.

Before adopting Flemming's no-threshold premise the House committee heard many witnesses on the opposite side of the debate, [FN7] and its *Report* acknowledges their contentions. *Id.* at 13 (witnesses stated that it was "possible to establish safe tolerance levels"). It also notes that some took the position that the ban should "apply only to colors that induce cancer when ingested in an amount and under conditions reasonably related to their intended use." ***1115 **356** *Id.* [FN8] Similarly, it notes support for making carcinogenicity simply one of the factors for the Secretary to consider in determining safety. *Id.* [FN9] Finally, it mentions a position taken by some scientific witnesses strikingly similar to that taken by FDA here. These experts suggested that, in spite of the difficulties in designing and evaluating tests for carcinogenicity, the Secretary "should have the authority to decide that a minute amount of a cancer-producing chemical may be added to man's food after a group of scientists consider all the facts and conclude that the quantity to be tolerated is probably without hazard." *Id.* at 13-14, U.S.Code Cong. & Admin.News 1960, p. 2895. [FN10]

> FN7. *See* Color Additives: Hearings Before the House Comm. on Interstate and Foreign Commerce, 86th Cong., 2d Sess. 115-18 (1960) [hereinafter *Color Additives Hearings*] (testimony of representative of the Toilet Goods Association) (arguing that risk from ingestion of lipstick colors did not justify absolute prohibition and

proposing amendment specifying that tests should be "appropriate" to proposed uses of additive for which listing was sought); *id.* at 224 (paper submitted by Edward J. Matson of Abbott Laboratories) ("One thing already accepted by most experts in the field is that there truly is a threshold dose of a carcinogen, below which cancer is not produced in animals ... [W]e cannot yet predict the threshold dose in man from knowledge of the threshold dose in experimental animals."); *id.* at 237-38 (representative of Manufacturing Chemists Association) ("there is lack of agreement among scientists as to whether a safe level can be set for all carcinogens"); *id.* at 260-61 (statement of representative of Pharmaceutical Manufacturers) ("when you consider conditions reasonably related to the intended use, I understand there is adequate scientific knowledge as to whether [an additive] could be used safely or not"); *id.* at 318 (representative of Pharmaceutical Manufacturers Association) (arguing that "as a practical matter, no-effect levels of carcinogens must be recognized" because "[w]e cannot dispense with the many common foods which are implicated in carcinogenicity").

FN8. For testimony advocating such a position, *see Color Additives Hearings* at 118, 224, 313; *see also id.* at 396 (Report of the Panel on Food Additives of the President's Scientific Advisory Committee) [hereinafter "Kistiakowsky Report"] ("dietary levels of carcinogenic agents exist at which the probability of cancer induction in animals is near zero").

FN9. Several industry representatives and other experts testified that the Delaney Clause was too inflexible as written and should be modified to permit greater administrative discretion. *See Color Additives Hearings* at 140-42 (testimony of representative of the Certified Color Industry Committee) (characterizing the provision as "an unwise, absolute rigid standard" and as lacking "any flexibility for future action" and proposing language to make carcinogenicity one of the factors considered in the general safety determination); *id.* at 237-38 (representative of Manufacturing Chemists Association) (arguing that requiring "the Secretary to return to Congress when a scientific breakthrough occurs injects inflexibility...." and anticipating problems such inflexibility could cause); *id.* at 266 (vice president of Eli Lilly & Co.) ("The main objection to the Delaney amendment is its rigidity."); *cf. id.* at 397 (Kistiakowsky Report states that "the panel believes that the probability of cancer induction from a particular carcinogen in minute doses may be eventually assessed by weighing scientific evidence as it becomes available").

FN10. *See Color Additives Hearings* at 429 (statement of Dr. Charles J. Kensler); *see also id.* at 468 (statement of Dr. William J. Darby) (favoring omission of Delaney Clause as long as there is "a law providing this adequate protection combined with ample provision for scientific review and judgment, plus publication of the basis of decisions").

The committee rejected all these positions on the grounds that they would "weaken the present anticancer clause." *Id.* at 13. The report responded to them with another quote from Secretary Flemming's hearing testimony, reflecting the view that agency discretion should cease once "a substance has been shown to produce cancer when added to the diet of test animals":

> The rallying point against the anticancer provision is the catch phrase that it takes away the scientists's [sic] right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge.... It allows the Department and its

> scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.

Id. at 14, U.S.Code Cong. & Admin.News 1960, pp. 2895-96.

Beyond this delineation of the intended scope of discretion, the *House Report* also addressed the possibility that its scientific premise--the absence of a threshold--might prove false. Its evident solution was that *Congress*, not the FDA, should examine the evidence and find a solution. The *House Report* at 12, U.S.Code Cong. & Admin.News 1960, p. 2894 quotes Secretary Flemming to precisely this effect:

> Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority. We believe, however, that the issue is so important that the elected representatives of the people should have the opportunity of examining the evidence and determining whether or not the authority should be granted.

See also Color Additives Hearings at 34 (administration statement that "if additional scientific evidence indicates that further ***1116 **357** relaxation of the Delaney amendment is desirable, it will of course be proposed").

The government and CFTA note that exempting substances shown by quantitative risk assessment to carry only trivial risks rests on a quite different foundation from establishing threshold levels below which no cancer is thought to occur. We agree that the two are distinguishable, but do not find the distinctions between them to cut in favor of a *de minimis* exception. If it is correct to read the statute as barring tolerances based on an assumed threshold, it follows *a fortiori* that the agency must ban color additives with real but negligible cancer risks.

House floor. In the House debate, little of substance occurred. Congressman Delaney contended that the anticancer provision was essential "if the public health is to be adequately protected," 106 Cong. Rec. at 14,350, and asserted in conclusory terms the inability to establish a safe dose or tolerance, *id.* Congressman Rogers, describing the anticancer clause (which he supported), observed that "[t]he 'safe for use' principle does not apply to situations where carcinogenicity is at issue." *Id.* at 14,371. One participant, Congressman Allen, expressed the view that the anticancer clause was "unnecessary and restrictive," and that the "decision on safety [should] be determined by the Secretary of Health, Education and Welfare rather than ... determined by law." *Id.* at 14,351. Accordingly, he urged passage of the Senate bill instead. Although Congressman Allen's view of the bill was negative, his interpretation seems to accord with that of its proponents: a ban follows automatically from a finding of carcinogenicity in man or animal.

Post-enactment Senate colloquy. The inferences of rigidity supported by the above remarks are drawn slightly in question--but ultimately, we think, not much--by an exchange that occurred the day *after* the Senate took final action on the final version of the Act. Senator Javits politely complained about the Senate's acting on this legislation in his absence. He secured unanimous consent for including in the Record the conclusions of a then-recent Report of the Panel on Food Additives of the President's Advisory Committee (the "Kistiakowsky Report"). He characterized the Report as stating that "authority such as that conferred by the amendment [the Report was addressed to the food additive Delaney Clause] should be used and applied within the 'rule of reason.' " 106 Cong. Rec. at 15,381. After Senators Dirksen and Hill assented to this proposition, Javits agreed to lay on the table a motion to reconsider the vote of the previous day. *Id.*

Appellees interpret the rule-of-reason colloquy as squarely supporting their *de minimis* approach, but in fact it is ambiguous. The Kistiakowsky Report defined "rule of reason" by a quotation from *Rathbun v. United States*, 355 U.S. 107, 109, 78 S.Ct. 161, 162, 2 L.Ed.2d 134 (1957): "Every statute

must be interpreted in the light of reason and common understanding to reach the results intended by the legislature." The proposition accords exactly with the way in which Judge Leventhal formulated the test for application of the *de minimis* doctrine: would the doctrine "implement[ ] the legislative design"? *Alabama Power,* 636 F.2d at 360. But that is the question, not the answer. Thus the exchange invoking the rule of reason appears to do no more than exhort us to pursue the inquiry we've been pursuing.

Indeed, although the Kistiakowsky Report itself points out some possible consequences of "a literal interpretation" of the food additive Delaney Clause, *see Color Additives Hearings* at 396-97, and states that in its interpretation the FDA "must employ the 'rule of reason' " as defined in *Rathbun, id.* at 398, it also acknowledges that clause may prevent the agency from "exercis[ing] discretion consistent with the recommendations of this report," *id.* Thus a commitment to the "rule of reason" in this context hardly carries an inexorable implication that the color additive Delaney Clause grants the FDA the discretion it now claims.

Taken as a whole, the remarks do not seem strong enough to undermine the inference ***1117 **358** we have drawn that the clause was to operate automatically once the FDA squeezed the scientific trigger. This is so even without regard to the usual hazards of post-enactment legislative history, which ordinarily lead to its being disregarded altogether. *See Regional Rail Reorganization Act Cases,* 419 U.S. 102, 132, 95 S.Ct. 335, 352, 42 L.Ed.2d 320 (1974) ("post-passage remarks of legislators, however explicit, cannot serve to change the legislative intent of Congress expressed before the Act's passage").

2. *Possible Explanations for an Absolute Rule*

Like all legislative history, this is hardly conclusive. But short of an explicit declaration in the statute barring use of a *de minimis* exception, this is perhaps as strong as it is likely to get. Facing the explicit claim that the Clause was "extraordinarily rigid," a claim well supported by the Clause's language in contrast with the bill's grants of discretion elsewhere, Congress persevered.

Moreover, our reading of the legislative history suggests some possible explanations for Congress's apparent rigidity. One is that Congress, and the nation in general (at least as perceived by Congress), appear to have been truly alarmed about the risks of cancer. *House Report* at 11; *Color Additive Hearings* at 327 (statement of Rep. Oren Harris, Chairman); *id.* at 491 (statement of Dr. Zavon) (Delaney Clause "tends to highlight the current hysteria regarding cancer"). This concern resulted in a close focus on substances increasing cancer threats and a willingness to take extreme steps to lessen even small risks. [FN11] Congress hoped to reduce the incidence of cancer by banning carcinogenic dyes, and may also have hoped to lessen public fears by demonstrating strong resolve. [FN12]

> FN11. *See Color Additives Hearings* at 341 (testimony of representative of Consumers Union) ("we are faced with an epidemic, an epidemic of cancer, a chronic disease, and ... all measures that will protect the public health should be taken, even at the cost of discomfort or sacrifice, financial sacrifice, to some segments of industry.").

> FN12. *Color Additive Hearings* at 327 (statement of Rep. Harris) (noting that "almost everyone[ ] is so conscious of cancer as a dread disease" and hypothesizing that throwing out the Delaney Clause "would create so much fear in the mind of the American people" that they might react against industry).

A second possible explanation for Congress's failure to authorize greater administrative discretion is that it perceived color additives as lacking any great value. For example, Congressman Delaney remarked, "Some food additives serve a useful purpose.... However, color additives provide no nutrient value. They have no value at all, except so-called eye appeal." *Color Additives Hearings* at

108. Representative Sullivan said, "we like the bright and light [lipstick] shades but if they cannot safely be produced, then we prefer to do without these particular shades." *Id.* at 114. And Representative King: "The colors which go into our foods and cosmetics are in no way essential to the public interest or the national security.... [C]onsumers will easily get along without [carcinogenic colors]." *Id.* at 246-47.

It is true that the legislation as a whole implicitly recognizes that color additives are of value, since one of its purposes was to allow tolerances for certain dyes--harmful but not carcinogenic--that would have been banned under the former law. *See House Report* at 8-9; S.Rep. No. 795, 86th Cong., 1st Sess. 1-2 (1959). There was also testimony pointing out that in some uses color additives advance health: they can help identify medications and prevent misapplications where a patient must take several. *See Color Additives Hearings* at 255 (statement of representative of Pharmaceutical Manufacturers Association). Nevertheless, there is evidence that Congress thought the public could get along without carcinogenic colors, especially in view of the existence of safer substitutes. Thus the legislators may have estimated the costs of an overly protective rule as trivial.

So far as we can determine, no one drew the legislators' attention to the way in which the Delaney Clause, interacting with the flexible standard for determining safety ***1118 **359** of non-carcinogens, might cause manufacturers to substitute more dangerous toxic chemicals for less dangerous carcinogens. *See* discussion at [10] *supra.* But the obviously more stringent standard for carcinogens may rest on a view that cancer deaths are in some way more to be feared than others.

Finally, as we have already noted, the House committee (or its amanuenses) considered the possibility that its no-threshold assumption might prove false and contemplated a solution: renewed consideration by Congress.

Considering these circumstances--great concern over a specific health risk, the apparently low cost of protection, and the possibility of remedying any mistakes--Congress's enactment of an absolute rule seems less surprising.

C. *Special Arguments for Application of de Minimis*

Apart from their contentions on legislative history, the FDA and CTFA assert two grounds for a *de minimis* exception: an analysis of two cases applying *de minimis* concepts in the food and drug regulation context, and contentions that, because of scientific advances since enactment, the disallowance of *de minimis* authority would have preposterous results in related areas of food and drug law. (We treat an argument based on a new interpretation of the statutory language separately in section I-D.) We are, ultimately, not persuaded.

1. *De minimis cases*

Monsanto Co. v. Kennedy, 613 F.2d 947 (D.C.Cir.1979) (Leventhal, J.), considered whether acrylonitrile in beverage containers was a "food additive" within the meaning of the Food, Drug and Cosmetic Act's definition of that term:

> 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 ... if such substance is not generally recognized ... to be safe under the conditions of its intended use ...

Section 201(s), Food, Drug and Cosmetic Act, 21 U.S.C. § 321(s) (1982).

By operation of the second law of thermodynamics, any substance, obviously including acrylonitrile, will migrate in minute amounts from a bottle into a beverage within the bottle. Questions had been raised about its safety. The court found the FDA's decision to ban its use insufficiently well considered. In remanding the case for reconsideration, the court emphasized the FDA Commissioner's discretion to exclude a chemical from the statutory definition of food additives if "the level of migration into food ... is so negligible as to present no public health or safety concerns." *Id.* at 955.

The opinion makes no suggestion that anyone supposed acrylonitrile to be carcinogenic, or that the Delaney Clause governing food additives, 21 U.S.C. § 348(c)(3)(A), was in any way implicated. Thus the case cannot support a view that the food additive Delaney Clause (or, obviously, the color additive one) admits of a *de minimis* exception. [FN13]

> FN13. As we note below, the operation of the food additive Delaney Clause raises complex issues distinct from those of this appeal.

Scott v. Food and Drug Administration, 728 F.2d 322 (6th Cir.1984) (*per curiam*), involves the color additive Delaney Clause, but is nonetheless distinguishable. Petitioner challenged the FDA's listing of Green No. 5, on the grounds that it contained a chemical impurity in minute quantities that had been found to cause cancer in test animals. The dye as a whole, however, had been found not to induce cancer in test animals. *See* 47 Fed.Reg. 49,628, 49,629 (1984). The Sixth Circuit upheld the FDA's decision that the Delaney Clause of the Color Additive Amendments did not apply. The court cited *Monsanto* in support of upholding the FDA's view that it had discretion "to find that low-level migration into food of substances in *indirect* additives is so insignificant as to present no ***1119 **360** public health or safety concerns." *Id.* at 325 (quoting the FDA's statement of its own discretion) (emphasis added).

We must evaluate *Scott* in light of the possibility that the carcinogenic impurity in question acted as an "initiating agent" or was a "complete carcinogen," *see* note 6 *supra*, and, accordingly, would be subject to no threshold. If so, it would seem that if the impurity itself were carcinogenic, so would be any substance to which it was added.

Application of a *de minimis* exception for *constituents* of a color additive, however, seems to us materially different from use of such a doctrine for the color additive itself. As the *Scott* court noted, the FDA's action was completely consistent with the plain language of the statute, as there was no finding that the *dye* caused cancer in animals. 728 F.2d at 325. Here, as we have observed, application of a *de minimis* exception requires putting a gloss on the statute qualifying its literal terms.

Monsanto and *Scott* demonstrate that the *de minimis* doctrine is alive and well in the food and drug context, even on the periphery of the Delaney Clauses. But no case has applied it to limit the apparent meaning of any of those Clauses in their core operation.

2. *Scientific Advance and the Implications for Food Additive Regulation*

The CTFA also argues that in a number of respects scientific advance has rendered obsolete any inference of congressional insistence on rigidity. CTFA notes that while in 1958 (date of enactment of the food additive Delaney Clause) there were only four known human carcinogens, by 1978 there were 37 substances known to produce cancer in humans and over 500 in animals. They identify an impressive array of food ingredients now found to be animal carcinogens and that appear in a large number of food products. These include many items normally viewed as essential ingredients in a healthy diet, such as vitamins C and D, calcium, protein, and amino acids. If the color additive Delaney Clause has no *de minimis* exception, it follows (they suggest) that the food additive one must be equally rigid. The upshot would be to deny the American people access to a healthy food supply.

As a historical matter, the argument is overdrawn: the House committee was clearly on notice that certain common foods and nutrients were suspected carcinogens. [FN14]

> FN14. *See Color Additives Hearings* at 270 (statement of vice-president of Eli Lilly) (noting substances implicated in carcinogenicity in animals, including coffee, tea, milk, cream, cocoa, claret, caffeine, whiskey, sulfonamides, fat, cholesterol, vitamins, eggs, sugars, and others); *id.* at 318, 328 (testimony of Representative of Phar-

maceutical Manufacturers' Association) ("so many of our common foods do contain carcinogens"); *id.* at 337-38 (testimony of representative of Consumers' Union) ("the fact that weak carcinogens are present in natural foods is no justification" for tolerances for carcinogenic additives); *id.* at 342 (statement of Rep. Nelson) ("we have been told that, for example, hens' eggs, milk, beef, soybeans, corn, lettuce alfalfa, have certain factors in them that create cancer"); *id.* at 397 (Kistiakowsky Report) ("In foodstuffs, as they occur in nature, one finds traces of chemicals which in larger amounts are generally accepted as carcinogenic...."); *id.* at 427 (Rep. Flynt) (asking witness whether it was "substantially true that nearly every element of food known at the present time if either injected or ingested in large quantities is capable of producing cancer first or toxicity secondly?").

Beyond that, it is not clear that an interpretation of the food additive Delaney Clause identical with our interpretation of the color additive clause would entail the feared consequences. The food additive *definition* contains an exception for substances "generally recognized" as safe (known as the "GRAS" exception), [FN15] an exception that has no parallel in the color additive definition, 21 U.S.C. § 321(t)(1). That definition may permit a *de minimis* ***1120 **361** exception at a stage that logically precedes the FDA's ever reaching the food additive Delaney Clause. Indeed, *Monsanto* so holds--though, as we have noted, in a case not trenching upon the food additive Delaney Clause. Moreover, the GRAS exception itself builds in special protection for substances used in food prior to January 1, 1958, which may be shown to be safe "through either scientific procedures or experience based on common use in food." Indeed, the Kistiakowsky Report, filed with the House committee, stated that the grandfathering provision of the food additives Delaney Clause "considerably narrows [its] effect ... on industry and the public." *See Color Additives Hearings* at 395.

FN15. The pertinent part of 21 U.S.C. § 321(s) excepts a substance

> 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....

The relationship of the GRAS exception and the food additive Delaney Clause clearly poses a problem: if the food additive definition allows the FDA to classify as GRAS substances carrying trivial risks (as *Monsanto* and our recent decision in *Natural Resources Defense Council v. EPA* seem to suggest), but the food additive Delaney Clause is absolute, then Congress has adopted inconsistent provisions. *Cf. Color Additives Hearings* at 313 (representative of Pharmaceutical Manufacturers Association testifies that Secretary Flemming will propose legislation to delete the grandfathering provision from the food additives definition because of inconsistency with the food additives Delaney Clause). On the other hand, if (1) the GRAS exception does not encompass substances with trivial carcinogenic effect (especially if its special provision for substances used before 1958 does not do so for long-established substances), and (2) the food additive Delaney Clause is as rigid as we find the color additive clause to be, conceivably the consequences identified by the CTFA, or some of them, may follow. All these are difficult questions, but they are neither before us nor is their answer foreordained by our decision here.

Moreover, we deal here only with the color additive Delaney Clause, not the one for food additives. Although the clauses have almost identical wording, the context is clearly different. Without having canvassed the legislative history of the food additive Delaney Clause, we may safely say that its proponents could not have regarded as trivial the social cost of banning those parts of the American diet that CTFA argues are at risk.

Finally, even a court decision construing the food additive provisions to require a ban on dietary essentials would not, in fact, bring about such a ban. As Secretary Flemming noted, in words selected by the *House Report* for quotation, the FDA could bring critical new discoveries to Congress's attention. If the present law would lead to the consequences predicted, we suppose that the FDA would do so, and that Congress would respond.

D. *The Meaning of "[I]nduce Cancer"*

After Public Citizen initiated the litigation in No. 86-5150, the FDA published a notice embellishing the preamble to its initial safety determinations. 52 Fed.Reg. at 5081 (Orange No. 17); *id.* at 5083 (Red No. 19). These notices effectively apply quantitative risk assessment at the stage of determining whether a substance "induce[s] cancer in man or animal." They assert that even where a substance does cause cancer in animals in the conventional sense of the term, the FDA may find that it does not "induce cancer in man or animal" within the meaning of 21 U.S.C. § 376(b)(5)(B). It is not crystal clear whether such a negative finding would flow simply from a quantitative risk assessment finding the risk to be trivial for humans under conditions of intended use, or whether it would require a projection back to the laboratory animals: *i.e.*, an assessment that the risk would be trivial for animals exposed to the substance in quantities proportional to the exposure hypothesized for human risk assessment purposes. (Perhaps the distinction is without a difference.) In any event, the notices argued:

> The words "induce cancer in man or animal" as used in the Delaney Clause are terms of art intended to convey a regulatory judgment that is something more than a scientific observation that an additive is carcinogenic in laboratory animals. ***1121 **362** To limit this judgment to such a simple observation would be to arbitrarily exclude from FDA's consideration developing sophisticated testing and analytical methodologies, leaving FDA with only the most primitive techniques for its use in this important endeavor to protect public health. Certainly the language of the Delaney Clause itself cannot be read to mandate such a counterproductive limit on FDA's discharge of its responsibilities.

Id. at 5082; *id.* at 5084.

The notices acknowledged that the words "to induce cancer" had not been "rigorously and unambiguously" so limited in the previous notices. *Id.* at 5082; *id.* at 5084. This is a considerable understatement. The original determinations were quite unambiguous in concluding that the colors induced cancer in animals in valid tests; the explanations went to some trouble to rebut industry arguments to the contrary. Despite these arguments, FDA concluded that the tests demonstrated that the dyes were responsible for increases in animal tumors.

The plain language of the Delaney Clause covers all animals exposed to color additives, including laboratory animals exposed to high doses. It would be surprising if it did not. High-dose exposures are standard testing procedure, today just as in 1960; such high doses are justified to offset practical limitations on such tests: compared to expected exposure of millions of humans over long periods, the time periods are short and the animals few. [FN16] Many references in the legislative history reflect awareness of reliance on animal testing, [FN17] and at least the more sophisticated participants must have been aware that this meant high-dose testing. A few so specified. [FN18]

> FN16. *See, e.g.*, Office of Science and Technology Policy, "Chemical Carcinogens; Review of the Science and Its Associated Principles," 49 Fed.Reg. 21,594, 21,598 (1984) ("It is appropriate to use test doses that generally exceed human exposure levels in order to overcome the inherent insensitivity of the traditional design of the long-term animal test.").
>
> FN17. *See House Report* at 11 (explaining the Delaney Clause's foundation in experiments showing that "a number of substances when added to the diet of test animals have produced cancers of various kinds in the test animals"); *Color Additives*

Hearings at 46-47, 50-55 (summary of National Cancer Institute study describing animal testing techniques and describing uncertainties in predicting human responses from animal tests); *id.* at 74 (testimony of Secretary of HEW Flemming) ("anticancer clause constitutes sound public policy in view of the fact that no one knows how much or how little of a substance will induce cancer when added to the diet of man if it has been demonstrated that it will induce cancer when added to the diet of a test animal"); *id.* at 396 (Kistiakowsky Report) ("*Definition of induced cancer in animals*.... The criteria for defining whether or not a 'cancer' has been induced in experimental animals are varied."); *id.* at 424 (remark of Rep. Dingell); *id.* at 514 (testimony of Sec. Flemming) ("where those tests show that a substance will induce cancer when included in the diet of a test animal, ... it will be banned."); 106 Cong.Rec. 14,350 (1960) (remarks of Rep. Delaney) ("a number of these dyes have been shown to induce cancer in experimental animals, and are strongly suspected as being able to induce cancer in man."); *id* at 14,372 (remarks of Rep. Rogers) ("the point was made by scientific experts that many substances when administered to laboratory animals in certain quantities and under certain conditions are capable of inducing cancer.").

FN18. *See* 106 Cong.Rec. 14,372 (remarks of Rep. Kyl) (expressing reservations about Delaney Clause and stating "[t]he prohibition is based on the assumption that a substance which increases the incidence of cancer when included in the diet of animals at any dose may increase the incidence of cancer in man."); *Color Additive Hearings* at 396 (Kistiakowsky Report) (notes that food additive Delaney Clause prohibition "is based on the assumption that a substance which increases the incidence of cancer when included in the diet of animals at any dose level may increase the incidence of cancer when included in the diet of man even when present in amounts detectable only by the most sensitive analytical techniques.").

All this indicates to us that Congress did not intend the FDA to be able to take a finding that a substance causes only trivial risk in humans and work back from that to a finding that the substance does not "induce cancer in ... animals." This is simply the basic question--is the operation of the clause automatic once the FDA makes a finding of carcinogenicity in animals?--in a new guise. The only new argument offered in the notices is that, without the new ***1122 **363** interpretation, only "primitive techniques" could be used. In fact, of course, the agency is clearly free to incorporate the latest breakthroughs in animal testing; indeed, here it touted the most recent animal tests as "state of the art." The limitation on techniques is only that the agency may not, once a color additive is found to induce cancer in test animals in the conventional sense of the term, undercut the statutory consequence. As we find the FDA's construction "contrary to clear congressional intent," *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n. 9, 104 S.Ct. 2778, 2781 n. 9, 81 L.Ed.2d 694 (1984), we need not defer to it.

* * *

[1] In sum, we hold that the Delaney Clause of the Color Additive Amendments does not contain an implicit *de minimis* exception for carcinogenic dyes with trivial risks to humans. We based this decision on our understanding that Congress adopted an "extraordinarily rigid" position, denying the FDA authority to list a dye once it found it to "induce cancer in ... animals" in the conventional sense of the term. We believe that, in the color additive context, Congress intended that if this rule produced unexpected or undesirable consequences, the agency should come to it for relief. That moment may well have arrived, but we cannot provide the desired escape.

II. PROVISIONAL LISTING

The regulatory scheme of the Color Additive Amendments included grandfathering provisions for commercially established color additives. Pub.L. 86-618, tit. II, § 203, 74 Stat. 404 (uncodified provisions appearing at 21 U.S.C. § 376 note (1982)). These allowed provisional listing of established dyes pending testing for a two-and-a-half year period. They empowered the Secretary to extend the listing

> "for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive...."

Id. § 203(a)(2).

The process of completing these scientific investigations is only now being completed. When the litigation in No. 86-5150 began, ten color additives were on the provisional list. *Public Citizen v. Department of Health and Human Services*, No. 85-1573 (D.D.C. Feb. 13, 1986). Today, only three--Red No. 3, Red No. 33, and Red No. 36--remain.

Public Citizen petitioned for a ban on the provisionally listed colors; when the petition was denied, it sued in the court below. The court granted summary judgment for the FDA (and other appellees supporting provisional listing).

[2] In *McIlwain v. Hayes*, 690 F.2d 1041 (D.C.Cir.1982), this court set forth the guidelines governing challenges to the speediness of the Secretary's evaluations of provisionally listed dyes. The *McIlwain* court determined that agency discretion to postpone the expiration of provisional listings was limited only as follows: "Such postponements must be consistent with the public health, and the Commissioner must judge that the scientific investigations are going forward in good faith and will be completed as soon as reasonably practicable." *Id.* at 1047. The majority acknowledged that it was doubtful that Congress foresaw the advances in testing technology that occasioned the delays, but saw no reason to depart from the statute's plain language. *Id.*

McIlwain controls here. The FDA has found that the postponements for further evaluation of Red No. 3, Red No. 33, and Red No. 36 are consistent with the public health, that evaluations are going forward in good faith, and that they will be completed as soon as reasonably practicable. The agency carefully explained in its Federal Register notices and response to the rulemaking petition that extra time was needed for review of completed tests and in some cases the conduct of additional tests; a special scientific review panel was involved ***1123 **364** in this, and on completion of its work the agency would have to review its report. *See* 50 Fed.Reg. 35,783-84, 35,786- 89 (1985); 51 Fed.Reg. 31,323 (1986) (extension for Red No. 3 until Nov. 3, 1986); J.A. in No. 86-5150 at 387-421 (FDA Commissioner's response to Public Citizen's petition requesting ban). Announcing its most recent extension of Red No. 3, the agency explained that more time was needed "[b]ecause of the complexity of the scientific issues being considered." 51 Fed.Reg. at 39,85 6 (extension until Nov. 3, 1987). The most recent extensions for Red No. 33 and Red No. 36 announced that these reviews were essentially complete and the agency intended to list these dyes permanently, but that further time was necessary for the agency to prepare adequate explanations of its decisions. 52 Fed.Reg. 33,573 (1987) (extending provisional status until November 3, 1987); *see also id.* at 15,945 (extension for same dyes until July 6, 1987), *id.* at 6,323 (extension until May 4, 1987). Although *McIlwain* dealt specifically with delays caused by the need for further testing, its logic applies with equal force where further evaluation of completed tests is required. To the extent that Public Citizen's complaint rests on the length of time already taken and anticipated for review of these dyes, it is foreclosed by *McIlwain*. [FN19] Public Citizen's allegations of bad faith were not properly raised below, and in any event amount to no more than speculation.

FN19. We also find Public Citizen's claim

> that action on Red No. 3 has been "unreasonably delayed" under 5 U.S.C. § 706(1) to be without merit. Unreasonable delay must be determined in the statutory context. *Public Citizen Health Research v. Commissioner, Food & Drug Administration*, 740 F.2d 21, 35 (D.C.Cir.1984). As *McIlwain* suggested, the statutory scheme for grandfathering color additives allows the time necessary for careful testing and also for careful review of data.

Public Citizen also argues that provisional listing is permissible only when permanent listing is a reasonable possibility--an outcome precluded under this opinion if the outcome from the animal studies is positive. But this has not yet happened and may never happen. Neither Red No. 33 nor Red No. 36 has been found to induce cancer in humans or animals.

The situation is slightly less clear with regard to Red No. 3. The Commissioner explained, in denying Public Citizen's petition, that further evaluation was necessary to determine whether a carcinogenic effect observed in animal testing was caused by a secondary mechanism. J.A. in No. 86-5150, at 407-10. There was, to be sure, evidence linking a statistically significant increase in tumors to the dye, but the chain of causation has yet to be established. There was a possibility, the Commission explained, that the dye might have effected the rats' thyroid glands, with that effect in turn causing the tumors. *Id.* If this were established, then a no-effect level in rats might be established. *Id.; see also* 50 Fed.Reg. at 35,786-87. Until the agency arrives at a final decision as to this question, the question of the Delaney Clause's application is not ripe. We therefore express no opinion as to the applicability of the provision in this secondary-effect situation, and decline to disturb the judgment of the District Court.

CONCLUSION

In sum, we hold that the agency's *de minimis* interpretation of the Delaney Clause of the Color Additive Amendments is contrary to law. The listing decisions for Orange No. 17 and Red No. 19 based on that interpretation must therefore be corrected. As for the colors still on the provisional list, we affirm the judgment of the court below in No. 85-5150, in view of *McIlwain* and the lack of a finding of carcinogenicity in the dyes at issue.

So ordered.

831 F.2d 1108, 56 USLW 2269, 265 U.S.App.D.C. 349, 18 Envtl. L. Rep. 20,173

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