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In a number of regulatory settings, the regulated community has promoted the notion that regulators should recognize the concept of a de minimis risk level in establishing health-based standards. The idea of de minimis risk differs from risk-benefit balancing because risks are not compared with benefits. Instead, an activity's risks are compared with a relatively low level of risk, the de minimis level. The notion is that de minimis levels pose risks that ought to be acceptable to society; thus the idea of de minimis risk is also sometimes advanced as one way to interpret the objective of statutes that seek to "protect public health" or to ensure that a substance is "safe."

For advocates of the de minimis risk principle, how small is too small to be regulated? To answer this question, de minimis risk advocates typically employ a *comparative risk assessment*, arguing that the de minimis level for regulatory purposes should correspond to, or be slightly lower than, the risk associated with some general activity commonly thought to be "safe" (or at least thought to pose trivial risks). De minimis determinations at EPA and the Nuclear Regulatory Commission have been described this way:

> EPA and the Nuclear Regulatory Commission (NRC) . . . have proposed to set federal radiation standards using as a yardstick the fatality rates prevalent in industries commonly considered to be relatively safe. In its radiation protection proposal, EPA noted that "the risk of job-related accidental death in the safest of all major occupational categories, retail trades, [was] an annual death rate [of] 60 per million workers in 1975." This risk equates to a 45-year worklife risk of 2.7 in 1,000. The Agency based its proposed radiation protection guidelines on its finding that radiation risks of a magnitude similar to 3 in 1,000 "do not appear unreasonably high" because "they are comparable to risk of accidental death in the least hazardous occupations." In a similar vein, NRC's recent radiation protection proposal follows the approach recommended by the International Commission on Radiological Protection . . . which developed its guidelines by "comparing [radiation] risk with that of workers in industries . . . which are recognized as having high standards of safety." As NRC pointed out, "in such '[s]afe' industries . . . average annual mortality due to occupational hazards does not exceed 10^{-4}. . . ." This annual rate amounts to a 45-year lifetime risk in excess of 4 in 1,000. Like EPA, NRC proposed standards on the basis that occupational mortality risks due to radiation are "acceptable" if kept at or below this "safe industry" risk level. [Rodricks et al., Significant Risk Decisions in Federal Regulatory Agencies, 7 Regulatory Toxicol. and Pharmacol. 307 (1987).]

The de minimis principle has been litigated in a variety of contexts, including the Delaney Clauses. Enacted in the 1950s and 1960s, these provisions, all named after Congressman James Delaney (D-NY) who introduced them, prohibit the marketing or use of any food additive, color additive, or animal drug that is "found . . . to induce cancer in man or animal." 21 U.S.C. §376(b)(5)(B) (color additives), regardless of how small that risk of cancer might be. When the FDA sought to authorize the marketing of two color additives, Orange No. 17 and Red No. 19 (for use in cosmetics) on the grounds that the risk of cancer they posed was de minimis, Public Citizen sued to enforce the Delaney Clause's absolute bar. Public Citizen v. FDA, 831 F.2d 1108 (D.C. Cir. 1987).

Using QRAs, the FDA had estimated the risk of cancer from Orange No. 17 to be one in 19 billion at worst, and for Red No. 19 one in 9 million at worst. The FDA explained that it 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 court

of appeals agreed with the FDA that the risks were extremely small, relying in part on comparative risk assessments:

> Assuming that the quantitative risk assessments are accurate, as we do for these purposes, it seems altogether correct to characterize these risks as trivial. . . . 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). . . . 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. 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.
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> 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 concededly 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. [831 F.2d 1108, 1111.]

The court went on to note that the law does recognize as a general principle the idea of "the de minimis doctrine, shorthand for *de minimis non curat lex* ('the law does not concern itself with trifles')":

> The doctrine . . . serves a number of purposes. One is to spare agency resources for more important matters. 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.
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> 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.'" . . . Imposition of pointless burdens on regulated entities is obviously to be avoided if possible, 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.
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> 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. . . .
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> 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. 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 noncarcinogenic substances; if they did, the number of dyes passing muster might prove minuscule. 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." But the doctrine obviously is not available to thwart a statutory command; it must be interpreted with a view to "implementing the legislative design." Nor is an agency to apply it on a finding merely that regulatory costs exceed regulatory benefits. [831.F.2d 1108, 1112.]

Notwithstanding these considerations, the court invalidated FDA's decision, finding that the Delaney Clause permitted no de minimis exception. The question, said the court, is ultimately one of what Congress meant in the statute. The language of the Delaney Clauses did not acknowledge any exception and was absolute in its language. The legislative history also supported the idea that Congress intended an absolute bar. "[S]hort 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 [during congressional debate over the Clause] the explicit claim that the Clause was "extraordinarily rigid," . . . "Congress persevered."

Moreover, our reading of the legislative history suggests some possible explanations for Congress' 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. . . . This concern resulted in a close focus on substances increasing cancer threats and a willingness to take extreme steps to lessen even small risks. . . .

A second possible explanation for Congress' failure to authorize greater administrative discretion is that it perceived color additives as lacking any great value. For example, Congressman Delaney remarked, "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." . . . [T]here 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 of noncarcinogens, might cause manufacturers to substitute more dangerous toxic chemicals for less dangerous carcinogens. . . . 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' enactment of an absolute rule seems less surprising. . . . [831 F.2d at 1117-1118.]

NOTES AND QUESTIONS

1. The FDA's de minimis policy is but one of a variety of measures that the Agency has taken through the years, in an effort to breathe some flexibility into

an extremely rigid piece of legislation. Richard Merrill has depicted the policy as part of the "FDA's decade-long efforts to reconcile Congress's language with circumstances Congress may not have foreseen and for which it surely did not provide." He summarizes the factors that have induced FDA to seek escape from Delaney's literal meaning:

> Improvements in analytic chemistry have enlarged the universe of compounds that FDA regulates as food (and color) additives. More extensive testing of chemicals and more sensitive protocols have enhanced toxicologists' ability to identify substances capable of producing tumors, including several substances adopted for food use years ago [e.g., saccharin, which had been in use since the early 1900s, but was not found to be carcinogenic in animals until the early 1970s]. Some of these substances gained market acceptance long before their carcinogenicity was discovered. In addition to these science-driven pressures on regulators, the public health community's concerns about the relationship between diet and cancer have shifted focus. A consensus has emerged that dietary patterns influence cancer incidence. Investigators have also revealed that the human food supply is full of substances (most occurring naturally) that have been, or may be, shown to cause cancer in laboratory animals. [Merrill, FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?, 5 Yale J. on Reg. 1, 2-3 (1988).]

2. What is the relevance of the last two points Professor Merrill makes? On these points, see also Gold, Slone, Stern, Manley & Ames, Rodent Carcinogens: Setting Priorities, 258 Science 261 (1992); Ames, Dietary Carcinogens and Anticarcinogens: Oxygen Radicals and Degenerative Diseases, 221 Science 1256 (1983); Committee on Diet, Nutrition, and Cancer, Commission on Life Sciences, National Research Council, National Academy of Sciences, Diet, Nutrition and Cancer: Directions for Research (1982). Professor Bruce Ames has argued that it is a serious mistake to focus regulatory attention and economic resources on removing extremely low risks of cancer associated with man-made chemicals because humans are exposed to much greater cancer risks from their dietary patterns and the consumption of natural carcinogens and anticarcinogens. See Ames, Ranking Possible Carcinogenic Hazards, 236 Science 271 (1987). How did Public Citizen v. Young address these comparative risk considerations?

3. Ames's suggestion that naturally occurring substances are consistently riskier than man-made substances has been challenged by some researchers. Two researchers from the Columbia University School of Public Health reexamined Ames's data by including allegedly more representative examples of synthetic chemicals and more consistent measures of exposure. Their results suggest that risks ranging from large to small are presented by both natural and synthetic substances. See Perera & Boffetta, Perspectives of Comparing Risks of Environmental Carcinogens, 80 J. Nat'l Cancer Inst. 1282 (1988). They argue that few natural substances have been tested for carcinogenesis and that Ames has exaggerated the risks of exposure to naturally occurring carcinogens.

4. Public Citizen v. Young dealt only with the Delaney Clause applicable to color additives in section 706 of the FDCA, 21 U.S.C. §376(B)(5)(B), and not with the separate Delaney Clause applicable to food additives in section 409, 21 U.S.C. §348(c)(3)(A). The court noted that while "the clauses have almost identical wording, the context is clearly different" given the potentially greater social costs of banning certain food additives. 831 F.2d at 1117. Do you agree?

Citing this statement, EPA interpreted the food additives Delaney Clause to permit a de minimis exception when it establishes tolerances for pesticide residues on processed foods under section 409. 56 Fed. Reg. 7,750 (1991). EPA argued that since FIFRA contains no Delaney Clause and no Delaney Clause applies to pesticide residues on nonprocessed foods under section 408 of the FDCA, it would be irrational to apply the Clause strictly to processed foods. The Ninth Circuit rejected EPA's argument. It held that the interpretation of the color additives Delaney Clause in Public Citizen v. Young was "equally applicable" to the statutory language in section 409. Les v. Reilly, 968 F.2d 985, 989 (9th Cir. 1992). Finding the statutory language to be "clear and mandatory," the court explained that the legislative history indicates that "Congress intended the very rigidity that the language it chose commands." Id. at 988-989. The court refused EPA's invitation to distinguish between the color additives Delaney Clause and the clause governing food additives. It found that "Congress intended to ban all carcinogenic food additives, regardless of amount or significance of risk, as the only safe alternative." Id. at 989. Yet the court recognized that strict application of the Delaney Clause might not accomplish Congress's goal. It noted that consumers might switch to raw foods with pesticide residues that actually pose greater risks than the residues on processed foods that were at issue in the case.

5. The Clinton administration announced in May 1993 that it would seek to develop new food safety legislation in response to the *Les* decision. In June 1993, EPA, FDA, and the Department of Agriculture announced a major policy shift to promote reduced use of pesticides in food production. The agencies pledged a coordinated effort to remove high-risk pesticides from the market, and they endorsed integrated pest management, which emphasizes nonchemical pest-control alternatives. The new policy coincided with the release of a National Academy of Sciences report finding that existing regulatory policies failed to protect children adequately in light of their greater sensitivity to pesticide risks. National Research Council, Pesticides in the Diets of Infants and Children (1993). EPA had begun to consider reforms in the process for registering pesticides under FIFRA in July 1992 when the Agency requested public comment on how to structure regulatory incentives to encourage the development of safer pesticides. 57 Fed. Reg. 32,140 (1992). EPA indicated that it was considering accelerating the registration process for lower-risk pesticides and the possible restriction or removal of higher-risk pesticides for which safer substitutes become available. EPA policy that prohibits safety claims for pesticides also could be reconsidered in order to harness market forces to encourage the development of safer alternatives.

6. Concerned that EPA was not implementing the *Les* decision, NRDC subsequently sued EPA to force the elimination of carcinogenic residues on processed foods. In October 1994, EPA settled the lawsuit by agreeing to conduct an expedited review of previously approved uses for 36 pesticides believed to contain carcinogens. Cushman, EPA Settles Suit and Agrees to Move Against 36 Pesticides, N.Y. Times, Oct. 13, 1994, at A24. In February 1995, EPA announced that it would require that 34 pesticides be phased out of processed foods within two years and that it would review data on 87 other pesticides during the next five years. EPA's decision increased pressure in Congress to reform the Delaney Clause. McCoy, EPA Agrees to Ban Pesticides, Comply with Rule in Food Act, Wall St. J., Feb. 9, 1995, at B16.

7. In deciding Les v. Reilly, the court noted the cogency of the arguments for the EPA's position but held that the Delaney Clause was clear, categorical,

and dispositive. "If there is to be a change," the court added, "it is for Congress to direct." 968 F.2d at 990. The prospect that numerous high-volume pesticides would be removed from the market prompted the consensus enactment of the Food Quality Protection Act (FQPA) in 1996. The FQPA amended the food additives Delaney Clause to specify that it does not include pesticide chemical residues in raw or processed foods. 21 U.S.C. §321(s). Such residues are now governed by a new, health-based standard of "reasonable certainty of no harm," and this standard is extended to raw foods on which a much wider range of pesticides typically are used than the 80 to 100 chemicals used on processed foods. Advocates of strict tolerances for pesticides on foods were willing to forego the application of Delaney to pesticide residues on processed foods in return for the application of the new standard for pesticide residues on both raw and processed foods. The new standard requires "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all dietary exposures and all other exposures for which there is reliable information." Language in the legislative history, but not in the statute, suggests this reflects a policy to limit individual cancer risks to the exposed population to no greater than 1-in-1-million additional lifetime risk, although industry representatives are urging a more flexible interpretation. The FQPA also provides for a less onerous, expedited registration process for "minor use" pesticides, defined as those that are used on commercial crops where the crop is smaller than 300,000 acres, for which no alternative pesticides are available, and where other requirements are met. It also establishes some tolerance setting flexibility for such pesticides, which expose a smaller population to risk than higher-volume pesticides do. As of August 2006—the statutory date established for EPA to finish its work—the EPA had reassessed 9,637 tolerances out of a total of 9,721. These reviews resulted in recommendations to revoke 3,200 tolerances, modify 1,200, and leave 5,237 unchanged. See *http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_accomplishments.htm* (last viewed June 21, 2009).

8. How persuasive were the reasons for applying the Delaney Clause to food additives, as opposed to color additives, in the first place? Is the FQPA an improvement over the Delaney Clause approach to carcinogens in food additives?

9. In addition to the de minimis argument to which the court devoted most of its attention in Public Citizen v. Young, the Justice Department also argued that the two color additives did not "induce cancer within the meaning of the Delaney Clause," despite the FDA's previous finding to the contrary. This position, which "is difficult to reconcile with FDA's historical view, shared by other agencies, that high-dose animal tests are a reliable means for identifying human cancer hazards," Merrill, FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?, 5 Yale J. on Reg. 1, 85 (1988), was not taken seriously by the court.

B. Acceptable Risk and Section 112 of the Clean Air Act

The Delaney Clauses administered by the FDA are rare instances of a "zero-risk" regulatory scheme under current environmental laws. Until the Clean Air Act was amended in 1990, the section of the Clean Air Act regulating hazardous air pollutants, section 112, had been interpreted as another example of a zero-risk statute because it required EPA to provide an "ample margin of safety to protect the public health."