ES&T FEATURES

# Cancer risk management

*A review of 132 federal regulatory decisions*


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Various federal agencies are responsible for promulgating regulations and standards to protect the public from exposure to environmental carcinogens. Although many factors are considered in the decision to regulate a carcinogen, one important issue concerns the probability that individuals in an exposed population will develop cancer.

What has not been clear, however, is the level of cancer risk that triggers regulation, or whether there is consistency within and between agencies in arriving at the risk decisions that underpin regulatory action. We have retrospectively reviewed the use of cancer risk estimates in prevailing federal standards and in withdrawn regulatory initiatives to determine whether any simple patterns emerge to correlate risk level with regulatory action. Our results show that there are definite patterns and a surprising degree of consistency in the federal regulatory process.

The sources of the data reviewed are notices of proposed or final regulations found in the *Federal Register* and in published and unpublished regulatory support documents, all of which are in the public domain. Three measures of risk are considered: *Individual risk* is measured as an upper-limit estimate of the probability that the most highly exposed individual in a population will develop cancer as a result of a lifetime of exposure. The *size of the population* exposed to the hazards is considered. Finally, *population risk* is measured as an upper-limit estimate of the number of additional incidences of cancer in the exposed population. Federal agencies compute population risks (as measured by the number of cancer deaths per year) by one of two methods: by multiplying maximum individual risk by population size or by accounting for variations in individual exposure levels and adding up the resulting figures for an entire population. Almost one-third of the population risk estimates reviewed here were calculated using the first method, although the second method is preferable.

Knowledge of two additional terms, de manifestis and de minimis, is important to understanding the patterns that emerge from the data. *De manifestis* risk, literally a risk of obvious or evident concern, has its roots in the legal definition of an "obvious risk"; one that is instantly recognized by a person of ordinary intelligence. *De minimis* risk has been used for a number of years by regulators to define an acceptable level of risk that is below regulatory concern. This term stems from the legal principle, *de minimis non curat lex;* "the law does not concern itself with trifles."

Table 1 lists 132 regulatory decisions for which at least one of these measures of risk was estimated prior to regulation of the substance in question. The methods used by federal agencies for estimating individual risk are generally considered to overestimate risk; they assume maximum exposure and a linear no-threshold dose–response function. For example, the population risk estimate for saccharin (Number 100 in Table 1) is listed as 1200 cancer deaths annually, although the Food and Drug Administration (FDA) states that this is an upper-limit risk estimate and the actual risk is between zero and 1200.

The published maximum risk estimates have been taken at face value; any errors in the estimates or interagency differences in the approach to risk analysis are not considered impor-

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TABLE 1

**Preregulatory risk levels for chemical carcinogen exposures**

| Chemical decision | Agency | Individual lifetime risk (per $10^5$) | Exposed population size (millions) | Annual cancer cases | Reference |
|---|---|---|---|---|---|
| **Public** | | | | | |
| *Acrylonitrile* | | | | | |
| 1. Food | F | 0.01 | 220 | 0.01 | 49-FR-36635 |
| 2. Air | E1 | 380 | 220 | 0.5 | 50-FR-24312 |
| *Aflatoxins* | | | | | |
| 3. Corn | F | 70 | 34 | 90 | FDA Docket No. 78N-0048 |
| 4. Peanuts | F | 3 | 220 | 35 | |
| 5. *Aluminum tris* | E2 | 0.003 | — | — | 48-FR-50532 |
| 6. *Ambien* | E2 | 0.001 | — | — | 46-FR-17229 |
| *Amitraz* | | | | | |
| 7. Apples[a] | E2 | 0.2 | 220 | 6 | 44-FR-2678 |
| 8. Pears | E2 | 0.2 | 220 | 8 | 44-FR-2678 |
| *Arsenic* | | | | | |
| 9. Primary lead smelters | E1 | 0.7–10 | — | 0.006–0.1 | 48-FR-33112 |
| 10. Primary zinc smelters | E1 | 0.1–2 | — | 0.005–0.008 | 48-FR-33112 |
| 11. Zinc oxide plants | E1 | 20–300 | — | 0.002–0.02 | 48-FR-33112 |
| 12. Chemical manufacturers | E1 | 4–60 | — | 0.0008–0.1 | 48-FR-33112 |
| 13. Secondary lead smelters[a] | E1 | 21–340 | — | 0.04–6 | 48-FR-33112 |
| 14. High copper smelters[a] | E1 | 2300–36,000 | 0.37 | 1–18 | 48-FR-33112 |
| 15. Low copper smelters[a] | E1 | 430–6900 | 0.65 | 2 | 48-FR-33112 |
| 16. Glass manufacturers[a] | E1 | 64–1000 | 4.2 | 0.07–1 | 48-FR-33112 |
| 17. *Asbestos*[a] | E4 | 1–7 | — | — | 51-FR-3738 |
| 18. *Benomyl* | E2 | 0.7 | — | — | 47-FR-46747 |
| *Benzene* | | | | | |
| 19. Maleic anhydride plants | E1 | 8 | 10 | 0.03 | 49-FR-8386 |
| 20. Ethylbenzene styrene plants | E1 | 14 | 2.5 | 0.06 | 49-FR-8386 |
| 21. Storage vessels | E1 | 4 | 85 | 0.04 | 49-FR-8386 |
| 22. Coke byproduct[a] | E1 | 640 | 20 | 2 | 49-FR-23522 |
| 23. Fugitive emissions[a] | E1 | 20 | 30 | 0.5 | 49-FR-23498 |
| 24. Equipment leaks[a] | E1 | 50 | — | 0.1 | 49-FR-23498 |
| 25. Paint strippers[a] | C | 40 | — | — | 43-FR-21838 |
| 26. *Butadiene*[b] | E1 | 7600–30,000 | 52 | 18.5 | 50-FR-41466 |
| 27. *C.I. Vat Orange #1* | F | 0.000003 | — | — | 50-FR-20405 |
| 28. *Carbon tetrachloride*[b] | E1 | 700 | 230 | 70 | 50-FR-32621 |
| 29. *Chloroallyldiethiocarbamate* | E2 | 0.2 | — | — | 46-FR-27973 |
| *Chlorobenzilate* | | | | | |
| 30. U.S. population[a] | E2 | 0.3 | 210 | 8 | 44-FR-9548 |
| 31. Florida population[a] | E2 | 0.7 | 8 | 0.8 | 44-FR-9548 |
| *Chloroform*[b] | | | | | |
| 32. Water | E1 | 9 | — | 2 | 50-FR-39626 |
| 33. Waste | E1 | 2 | — | 0.5 | 50-FR-39626 |
| 34. *Chlorinated benzenes* | E1 | 0.2–1 | 6.5 | 0.0005–0.007 | 50-FR-32626 |
| 35. *Chlorothalonil* | E2 | 2 | — | — | 49-FR-45853 |
| 36. *Chromium*[b] | E1 | 1200–16,000 | 220 | 290 | 50-FR-24317 |
| 37. *Cinnamyl anthranillate*[a] | F | 0.1 | — | — | 47-FR-22545 |
| 38. *Coke oven emissions*[a] | E1 | 350–3600 | 0.12 | 2–6 | 41-FR-46742 |
| 39. *Cypermethrin* | E2 | 0.1 | — | — | 50-FR-1112 |
| 40. *Cyromazine* | E2 | 0.1 | — | — | 49-FR-18120 |
| 41. *Diallate*[a] | E2 | 10 | — | — | PD #4, 1982 |
| *1,2-Dibromo-3-chloropropane* | | | | | |
| 42. Peanuts[a] | E2 | 60 | 220 | 1900 | 44-FR-65151 |
| 43. Vegetable[a] | E2 | 60 | 220 | 1900 | 44-FR-65151 |
| *Dimethylnitrosamine* | | | | | |
| 44. Baby bottles[a] | F | 0.004 | — | — | FDA Docket No. 83D-0414 |
| 45. Paper, paperboard | F | 0.0005 | — | — | 50-FR-4643 |
| 46. *1,4-Dioxane* | F | 0.0000004 | — | — | 50-FR-36872 |
| *Epichlorohydrin* | | | | | |
| 47. Air | E1 | 1 | 220 | 0.001 | 50-FR-24575 |
| 48. Dimethylamine | F | 0.0000002 | — | — | 49-FR-13016 |
| 49. Polyamide | F | 0.001 | — | — | 49-FR-13021 |
| 50. *Ethalfluralin* | E2 | 0.4 | — | — | 49-FR-511 |
| 51. *Ethylene bisdithiocarbamates* | E2 | 50 | 220 | — | 47-FR-47669 |
| *Ethylene dibromide* | | | | | |
| Soil fumigant | | | | | |
| 52a. Food[a] | E2 | 1 | 230 | 36 | 48-FR-46228 |
| 52b. Water[a] | E2 | 8 | 230 | 25 | PD #4, 1983 |
| 53. Stored grain fumigant | E2 | 100 | — | — | PD #4, 1983 |
| 54. Spot grain fumigant[a] | E2 | 24 | 230 | 790 | 49-FR-4452 |
| 55. Quarantine fumigant[a] | E2 | 30 | 230 | 330 | 48-FR-46228 |
| 56. *Ethylene oxide*[b] | E1 | 200 | — | 60 | 50-FR-40286 |
| *Formaldehyde* | | | | | |
| 57. High school teachers | E4 | 3 | 0.038 | 0.02 | 49-FR-21870 |
| 58. High school students | E4 | 0.03 | 3.8 | 0.01 | 49-FR-21870 |
| 59. College teachers | E4 | 7 | 0.1 | 0.1 | 49-FR-21870 |
| 60. College students | E4 | 0.3 | 2.9 | 0.1 | 49-FR-21870 |
| 61. Medical students | E4 | 40.3 | 40.075 | 40.005 | 449-FR-21870 |
| 62. Dental students | E4 | 40.3 | 40.0215 | 40.001 | 449-FR-21870 |
| 63. Nursing students | E4 | 0.3 | 0.245 | 0.01 | 49-FR-21870 |
| 64. Mobile homes[b] | E4 | 13 | 4.2 | 8 | 49-FR-21870 |
| 65. Homes (non-urea-formaldehyde foam insulation) | E4 | 10 | 100 | 160 | 49-FR-21870 |
| 66. Rural air | E4 | 0.3 | 58 | 2 | 49-FR-21870 |
| 67. Urban air | E4 | 3 | 160 | 80 | 49-FR-21870 |
| 68. Particle board | E4 | 20 | — | 0.01 | 49-FR-21870 |
| 69. Homes (urea-formaldehyde foam insulation) | E4 | 5 | 1.8 | 1.3 | 49-FR-21870 |
| 70. Urea-formaldehyde insulation[a] | C | 9–30 | 1.8 | 23 | 46-FR-11188 |

| Chemical decision | Agency | Individual lifetime risk (per $10^5$) | Exposed population size (millions) | Annual cancer cases | Reference |
|---|---|---|---|---|---|
| *FD&C Yellow #5 (total)* | — | 0.04 | — | — | 50-FR-35774 |
| 71. 4-Aminoazobenzene | F | 0.00005–0.001 | — | — | 50-FR-35774 |
| 72. 4-Aminobiphenyl | F | 0.01 | — | — | 50-FR-35774 |
| 73. Aniline | F | 0.000004 | — | — | 50-FR-35774 |
| 74. Azobenzene | F | 0.00002 | — | — | 50-FR-35774 |
| 75. Benzidine | F | 0.03 | — | — | 50-FR-35774 |
| 76. 1,3-Diphenyltriazene | F | 0.0004 | — | — | 50-FR-35774 |
| *Gasoline products* | | | | | |
| 77. Bulk terminals[a] | E2 | 200–400 | — | 1–2 | 49-FR-31706 |
| 78. Service stations[a] | E2 | 4.4–7.2 | — | 3–6 | 49-FR-31706 |
| 79. Self-serve[a] | E2 | 6–9 | — | 20–30 | 49-FR-31706 |
| 80. *Lead acetate* | F | 0.02 | — | — | 45-FR-72112 |
| *Lindane* | | | | | |
| 81. Ornamental uses | E2 | 0.8 | 0.08 | — | 45-FR-45362 |
| 82. Dog dips[a] | E2 | 0.4 | 15 | — | PD #4, 1980 |
| 83. Shelf paper | E2 | 2 | 11 | — | PD #4, 1980 |
| 84. *Methoxychlor* | E2 | 0.005 | — | — | 45-FR-49117 |
| *Methylene chloride* | | | | | |
| 85. Decaffeinated coffee | F | 0.1 | 3.7 | 0.05 | 50-FR-51551 |
| 86. Aerosol cosmetics[a] | F | 10 | — | — | 50-FR-51551 |
| 87. Air[c] | E1 | 10 | — | — | 50-FR-42037 |
| 88. *4,4'-Methylenedianiline* | E4 | 0.1–2 | 0.03 | — | 48-FR-42898 |
| 89. *Methylenebis (o-chloroaniline)* | E4 | 0.3 | 0.03 | — | 48-FR-22954 |
| 90. *Metolachlor* | E2 | 0.1 | — | — | 47-FR-23932 |
| 91. *Oryzalin* | E2 | 0.06–0.5 | — | — | 49-FR-45854 |
| 92. *2,2'-Oxammidobis* | F | 0.007 | — | — | 48-FR-37616 |
| 93. *Oxyfluorfen* (perchloroethylene) diet | E2 | 0.1 | — | — | 47-FR-27118 |
| 94. *Pentachlorophenol*[a] | E2 | 100 | 0.02 | — | 49-FR-28666 |
| 95. *Polycyclic organic matter* | E1 | 7–20 | 220 | 200 | 49-FR-31680 |
| *Radionuclides* | | | | | |
| 96. Department of Energy facilities | E5 | 70 | 64 | 0.07 | 50-FR-5190 |
| 97. Nuclear Regulatory Commission, non-DOE facilities | E5 | 2 | — | 0.001 | 50-FR-5190 |
| 98. Elemental phosphorus | E5 | 100 | 3 | 0.06 | 50-FR-5190 |
| 99. Radon-222 uranium mill tailings[a] | E5 | 1000 | — | 3–6 | 51-FR-6382 |
| 100. *Saccharin* | F | 40 | 220 | 600–1200 | 42-FR-19996 |
| *Tetrachlorodibenzo-p-dioxin* | | | | | |
| 101. Local[a] | E2 | 20 | 0.0009 | 0.02 | 48-FR-48434 |
| 102. General[a] | E2 | 0.2 | 220 | 7.5 | 48-FR-48434 |
| *p-Toluidine* | | | | | |
| 103. D&C Green #5, #6 | F | 0.003 | — | — | 47-FR-24278 |
| 104. Diet | F | 0.007 | — | — | 47-FR-14138 |
| 105. Contact lenses | F | 0.00001 | — | — | 48-FR-13020 |
| 106. D&C Red #6, #7 | F | 0.002 | — | — | 47-FR-57681 |
| 107. *Trichloroethylene*[b] | E1 | 9 | — | 4 | 50-FR-52442 |
| 108. *Trifluralin* | E2 | 0.05 | — | — | PD #4, 1985 (OTS, 1982)[c] |
| 109. *Trihalomethanes*[a] | E3 | 40 | 230 | 340 | 47-FR-9796 |
| *Vinyl chloride* | | | | | |
| 110. Ethylene dichloride–vinyl chloride monomer plants[a] | E1 | 260 | 5 | 0.6 | 50-FR-1182 |
| 111. Polyvinyl chloride plants[a] | E1 | 900 | 5 | 16 | 50-FR-1182 |
| 112. Food (polymers) | F | 0.01 | — | — | 51-FR-4173 |
| 113. *Vinylidene chloride* | E1 | 80 | — | 0.07 | 50-FR-32632 |
| **Occupational** | | | | | |
| *Amitraz* | | | | | |
| 114. Pears | E2 | 10 | 0.005 | 0.004 | 44-FR-2678 |
| 115. Apples[a] | E2 | 10 | 0.005 | 0.002 | 44-FR-2678 |
| 116. *Arsenic*[a] | O | 200–300 | — | 380 | 48-FR-1864 |
| *Asbestos* | | | | | |
| 117. 20 Fibers/cm[3a] | O | 17,000 | 0.4 | 180 | 49-FR-14120 |
| 118. 2 Fibers/cm[3a] | O | 6400 | 0.4 | 90 | 49-FR-14120 |
| 119. *Benzene*[a] | O | 4400-15,200 | 0.05 | 44–150 | 50-FR-50512 |
| 120. *Chlorobenzilate* | E2 | 140 | 0.07 | 0.01 | 44-FR-9548 |
| *1,2-Dibromo-3-chloropropane* | | | | | |
| 121. Citrus[a] | E2 | 9300 | — | 0.05 | Final PD, 1979 |
| 122. Cotton[a] | E2 | 10 | — | 0.001 | 44-FR-65151 |
| 123. Peaches[a] | E2 | 360 | — | 0.6 | 44-FR-65151 |
| 124. Pineapple | E2 | 9 | — | 0.001 | 49-FR-1556 |
| 125. Soybeans[a] | E2 | 9 | — | 0.01 | 44-FR-65151 |
| *Ethylene dibromide* | | | | | |
| 126. OSHA[a] | O | 7000–11,000 | 0.0006 | 1.5 | 48-FR-45958 |
| 127. Soil fumigant[a] | E2 | 3500 | 0.014 | 0.7 | 48-FR-46228 |
| Spot grain fumigant | | | | | |
| 128. Millworkers[a] | E2 | 2000 | 0.016 | 5 | 49-FR-4452 |
| 129. Applicators[a] | E2 | 10,000 | 0.006 | 9 | PD #4, 1984 |
| 130. Quarantine fumigant[a] | E2 | 30,000 | — | 0.5 | PD #4, 1984 |
| 131. *Ethylene oxide*[a] | O | 6300–11,000 | 0.07 | 70 | 49-FR-25734 |
| *Tetrachlorodibenzo-p-dioxin* | | | | | |
| 132. Rights-of-way brush[a] | E2 | 350 | 0.086 | 0.1 | 48-FR-48434 |

[a]Agency acted to reduce risk.
[b]No regulatory decision has been made.
[c]Office of Toxic Substances, EPA.

**Agency key**
C = Consumer Product Safety Commission
E = Environmental Protection Agency
E1 = Office of Air Quality Planning and Standards
E2 = Office of Pesticide Programs
E3 = Office of Drinking Water
E4 = Office of Toxic Substances
E5 = Office of Radiation Programs
F = Food and Drug Administration
O = Occupational Safety and Health Administration

**Source key**
FR = Federal Register
PD = Position Document

FIGURE 1
**Preregulatory levels of maximum individual lifetime risk reviewed by federal agencies**

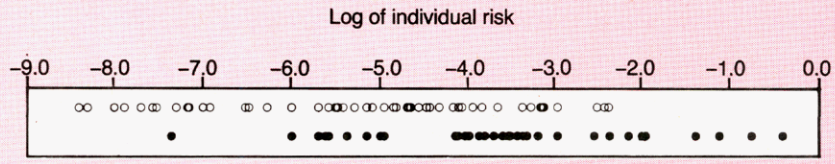



**Figure Key:** ○ = Agencies did not act to reduce public risk; • = agencies acted to reduce public risk; □ and ■ = action taken or not taken, respectively, for occupational risk; + = no regulatory decision has been made.

tant for our analysis. All that matters is that when the regulatory decision was made, risk managers were presented with these estimates as the best available upper-bound estimates.

### Categories of risk

Figure 1 presents preregulatory levels of maximum individual risk for regulatory decisions involving public exposure to chemical carcinogens. Two patterns are apparent. First, every chemical with an individual risk above $4 \times 10^{-3}$ (four chances in 1000 that a chronically exposed individual will develop cancer) was regulated. Second, except for one FDA decision (Number 44 in Table 1), no action was taken to reduce individual lifetime risk levels that were below $1 \times 10^{-6}$.

The Delaney Clause of the Federal Food, Drug and Cosmetic Act Food Additives Amendment of 1958 states: "No additive shall be deemed safe if it is found to induce cancer when ingested by man or animal." Despite this, in all 11 decisions made between 1980 and 1985 involving indirect carcinogenic food additives, FDA set standards but did not require existing risk levels to be reduced. FDA has recently argued that the Delaney Clause permits use of carcinogenic food additives with cancer risks below $1 \times 10^{-6}$; a decision that is being challenged in court. Our analysis shows that FDA's reasoning is consistent with historical practice.

Figure 2 presents 58 cases in which estimates of both individual risk and population size were available at the time a regulatory decision was made. Estimated exposed populations ranged from 9700 to 230 million, the latter for the total U.S. population. There does not appear to be a strong correlation between the size of the population exposed and the likelihood of regulation. This conclusion is contrary to that reached by Milvey, who stated that the de minimis risk level is a function of the size of the population at risk (*1*). To further investigate this question, we review estimates of individual and population risk.

Figure 3 presents decisions for which individual and population risk estimates were available at the time of regulation. Three categories of risk can be identified. De manifestis risks are those that are so high that agencies almost always acted to reduce them, and de minimis risks are so low that agencies almost never acted to reduce them (*2*). The risks falling into the area between these extremes were regulated in some cases but not in others.

Figure 4 shows 19 occupational decisions that have been added to Figure 3 to provide data on small populations at high individual risk; no other data exist for these cases. It is assumed that decisions to regulate occupational exposures can be used to aid in defining de manifestis and de minimis risk levels because public exposures to carcinogenic substances should be regulated at least as stringently as occupational exposures are.

Line A of Figure 4 defines the de manifestis level; above this line, federal agencies always acted to reduce risk. For exposures resulting in a small-population risk, the de manifestis level is approximately $4 \times 10^{-3}$. As population risk approaches 250 cancer deaths (which could only occur in a population the size of the entire United States) the de manifestis level drops to about $3 \times 10^{-4}$. Line B shows the de minimis level. Below this line, no action has ever been taken to reduce risk. Line B indicates that for small-population effects, regulatory action was never taken for individual risk levels below $10^{-4}$. For effects resulting from exposures to the entire U.S. population, the level of acceptable risk drops to $10^{-6}$. Line C is the area beyond which no data can fall. Figure 4 is essentially an analysis of the Reagan administration's regulatory decisions; only six decisions in Figure 4 occurred before 1980.

Figure 4 raises two questions. First, what justification is given by regulatory

FIGURE 2
**Effect of individual risk vs. population size on chemical carcinogen regulations**

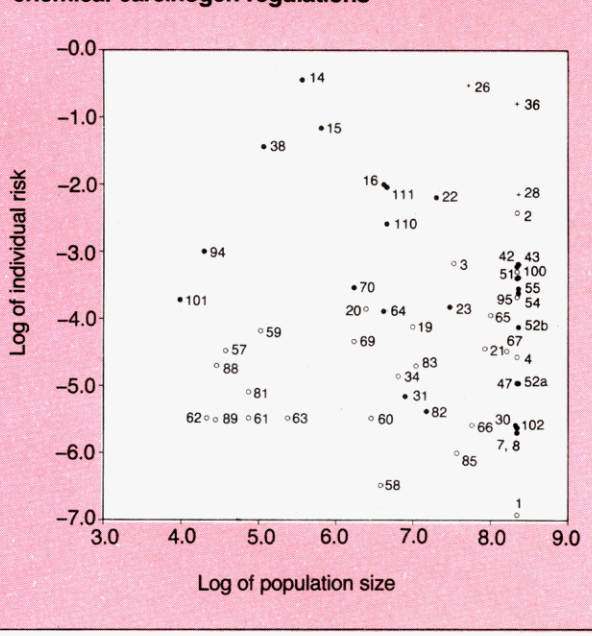



FIGURE 3
**Effect of individual vs. population risk on chemical carcinogen regulation**

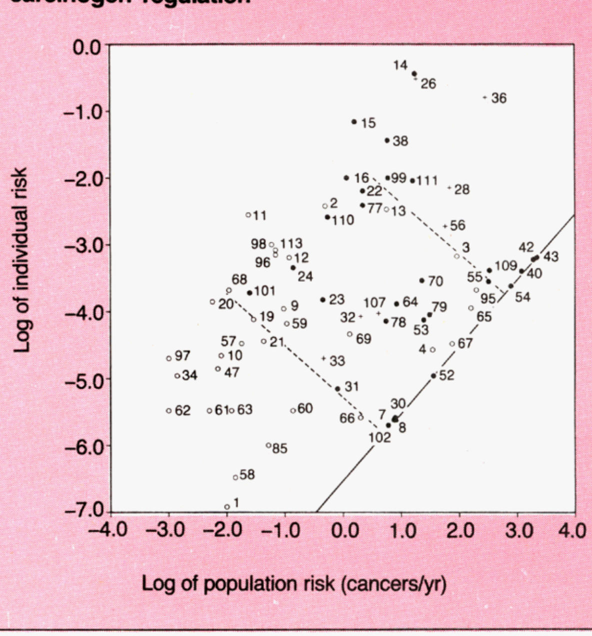


FIGURE 4
**Effect of individual vs. population risk on chemical carcinogen regulation**

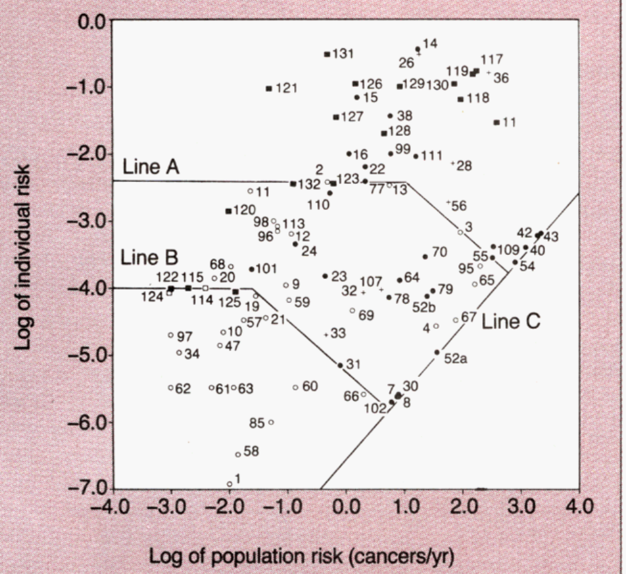
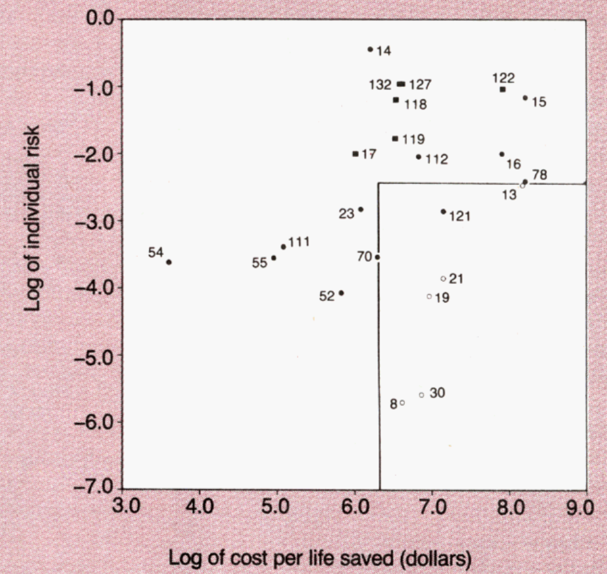



FIGURE 5
**Effect of cost on the regulation of chemical carcinogens**




agencies for not regulating chemicals in the de minimis category of risk? Second, what justification is given for regulatory decisions involving chemicals in the region between the de manifestis and de minimis levels? The primary answer given by federal agencies to the first question, as defined in Figure 4, is insignificant population risk. Table 2 shows those regulatory decisions that cited insufficient risk as the reason not to regulate. EPA's most explicit statement on the use of population effects in setting acceptable levels of risk is found in its decision on radionuclide standards (Table 1, Numbers 96–99).

In declining to regulate natural radionuclide emissions from elemental phosphorus plants (with an individual risk of $1 \times 10^{-3}$), the EPA decision states, "If risk to the most exposed individuals were the only criterion for judgment, this relatively high risk might well have led to a decision to regulate. However, this risk must be weighted against both the low aggregate risk [0.06 cancer deaths per year] and against other factors," such as cost (*3*).

Only two decisions in the de minimis region of Figure 4 consider factors other than small-population risk. Arsenic emissions from zinc smelters and benzene emissions from storage vessels are regulated by Section 112 of the Clean Air Act, the enforcement of which is heavily influenced by available technology. At the time of regulation, these two sources were already controlled with the best available technology (BAT), and further regulation could have resulted in shutdown of the industry (*4, 5*).

Analysis of regulatory decisions involving chemicals in the region between the de manifestis and de minimis levels indicates that cost effectiveness is the primary determinant of regulation. Figure 5 shows the cost effectiveness (cost per life saved) of regulating exposures to 23 chemicals vs. their preregulatory individual lifetime risk. Substances with individual risks above the de manifestis level were regulated regardless of cost.

In the region between the de manifestis and de minimis levels, substances with risk reduction costs of less than \$2 million per life saved were regulated; substances that cost more were not regulated. This conclusion is based on limited data, but it is consistent with EPA guidance suggesting that regulation is warranted if the cost per life saved does not exceed \$1.5 million (*6*).

The two major factors that influence the magnitude of cost, and by extension the decision to regulate, are the availability of substitutes (for example, decisions 8 and 30) and whether emissions currently are controlled by BAT (for example, decisions 9–13 and 19–21).

In reviewing the regulatory decisions of the past decade, two trends are apparent. First, there is an increased use of quantitative risk analysis, which extrapolates animal data to humans. Between 1976 and 1980, quantitative risk analysis was used in regulatory decisions involving only eight chemicals; from 1981 to 1985 the number of decisions increased to 53. Second, there are indications that the definition of de minimis is changing.

Prior to 1980, it was generally agreed that the de minimis risk was $10^{-6}$ per lifetime risk, regardless of population. Figure 4 indicates that for small-population risks, the de minimis risk is now considered to be a $10^{-4}$ lifetime risk. However, every decision in the de minimis region of Figure 4 was made after 1983.

### Regulatory guidelines

The Environmental Protection Agency has specifically requested assistance in developing a quantitative rule for incorporating population risk into the decision-making process (*7*). EPA has suggested a de minimis individual lifetime risk level of $10^{-5}$ to $10^{-4}$ for small populations and $10^{-7}$ to $10^{-6}$ for large populations. Although no such explicit standard has been developed, we can see that there are simple rules that can be used to guide regulatory decisions. These guidelines incorporate individual risk, population risk, and cost effectiveness into a single framework, even though it is recognized that no absolute rules are possible.

**Guideline 1.** There is a de manifestis individual lifetime risk level that is a function of population risk, as shown in Line A of Figure 4. Above this level, regulatory action should be taken to reduce risk.

**Guideline 2.** There is a de minimis individual lifetime risk level that is a function of population risk, as shown in Line B of Figure 4. Below this line, regulatory action generally need not be taken.

**Guideline 3.** In the region between the de manifestis and de minimis levels, regulatory action should be taken if the

TABLE 2
**Decisions citing insignificant population risk as the reason not to regulate**

| Chemical | Individual risk | Population risk (cancer/yr) | Agency comments |
|---|---|---|---|
| **Arsenic** | | | |
| Zinc oxide | $3 \times 10^{-3}$ | 0.02 | *Total cancer incidence, even on a national basis, is likely to be small compared to the incidence associated with smoking and diet.* |
| Secondary lead smelters | $3 \times 10^{-3}$ | 6 | |
| Primary lead smelters | $1 \times 10^{-4}$ | 0.1 | |
| Chemical manufacturing | $6 \times 10^{-4}$ | 0.1 | |
| Zinc smelters | $2 \times 10^{-5}$ | 0.008 | |
| **Radionuclides** | | | |
| Elemental phosphorus | $1 \times 10^{-3}$ | 0.06 | *This risk [$10^{-3}$ individual risk] must be weighed against both the low aggregate risk and against other factors.* |
| **Vinylidene chloride** | $8 \times 10^{-4}$ | 0.07 | *Magnitude of the public health risk is small.* |
| **Radionuclides** | | | |
| Department of Energy facilities | $7 \times 10^{-4}$ | 0.07 | *[Population impact] insufficient to warrant regulation.* |
| Nuclear Regulatory Commission, non-DOE | $2 \times 10^{-5}$ | 0.001 | |
| **Formaldehyde** | | | |
| Teachers | $7 \times 10^{-5}$ | 0.1 | *[Population risk below one cancer risk per year, which is] insignificant risk of widespread harm.* |
| Students | $3 \times 10^{-6}$ | 0.001–0.1 | |
| **Chlorinated benzenes** | $1 \times 10^{-5}$ | 0.007 | *Health risk is not sufficient to warrant regulation.* |
| **Epichlorohydrin** | $1 \times 10^{-5}$ | 0.001 | *Relatively low aggregate risk.* |

cost is below $2 million per life saved.

These guidelines have significant implications, for example, concerning remedial action at hazardous-waste sites. Most such sites pose risk to only a limited geographic area, where population risks presumably are small. Past regulatory actions by EPA indicate that $10^{-4}$ would be the de minimis risk level for these areas.

Perhaps the most surprising aspect of our study is the consistency found among federal agencies' methods in the use of cancer risk estimates for regulatory decisions. With the possible exception of FDA decisions concerning de minimis risks, the history of federal decision making indicates that all agencies are fairly consistent in their implicit definitions of de manifestis and de minimis levels of risk. If the above three guidelines were adopted explicitly, consistency with past decisions would be maintained and the process of regulatory decision making would be simplified considerably.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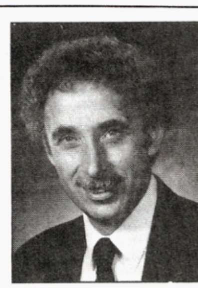


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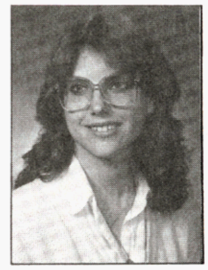


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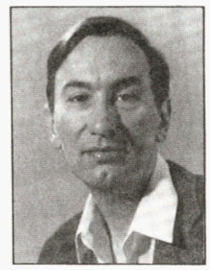


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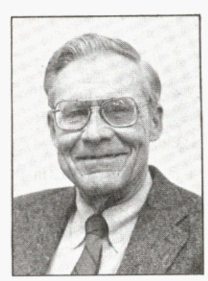


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