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Risk and Benefit

In any legislation affecting public health the possible risks must be considered in relation to the possible benefits, and when the risks cannot be determined with certainty, reasonable and well-informed men may disagree about the best course to be followed. One approach is to avoid risk, however slight, entirely. This is the course that has been followed for food additives since the Delaney proviso of the Amendment of the Food, Drug, and Cosmetic Act of 1958 went into effect. The proviso states that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal . . . ."

Secretary Flemming of the Department of Health, Education, and Welfare, acting under this amendment, barred the sale of cranberries that had been sprayed with aminotriazole, and of fowl that had been treated with stilbestrol. He now proposes that the same proviso be extended to the companion bills pending before the House and Senate (H.R. 7624 and S. 2197), which will "authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used."

In support of his recommendation Flemming cites several sources, among them the statement by the Food Protection Committee of the National Academy of Sciences–National Research Council that extrapolation from the levels of carcinogens (cancer-inducing substances) in the diets of animals to safe levels for man is "currently impossible," and the conclusion in a review by G. Burroughs Mider of the National Cancer Institute that "No one at this time can tell how much or how little of carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop."

What the Secretary is advocating in effect is that at present he be given no administrative discretion for permitting the use of possible carcinogens as food additives under any conditions and at any concentrations.

Last week the Panel on Food Additives of the President's Science Advisory Committee took issue with this position. (Excerpts from the panel's report appear on page 1596. The panel points out that for many carcinogens there is evidence for the existence of a level of ingestion at which no carcinogenesis occurs during the lives of the animals tested and that dose-response curves have been worked out which allow prediction of the probability of cancer induction from a given dose. The panel also cites evidence to show that a dose-response relationship holds in certain human cancers.

On the basis of this and other evidence, the panel differs sharply from Secretary Flemming in recommending (i) that administrative discretion is essential now, rather than in the future, for deciding whether or not the use of certain possibly carcinogenic compounds as food additives should be prohibited; and (ii) that if such discretion does not now exist, the law should be modified. The panel proposes that an advisory board be appointed to assist the Secretary in evaluating the scientific evidence.

If the panel's recommendations are followed, it will be possible to consider each case on its merits—on the basis of risk relative to benefit—rather than to condemn all without the exercise of scientific judgment.—G.DuS.