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Zero Tolerance

At a date still to be set for sometime next month, the House Committee on Interstate and Foreign Commerce will assemble a panel of scientists for hearings on food additives. The use of cancer-inducing substances (carcinogens) as food additives, which has been brought prominently to public attention by the recent cranberry incident and the barring from the market of fowl treated with a synthetic female sex hormone that can induce cancer under laboratory conditions, will undoubtedly be a major issue.

Central to this issue is the controversial "Delaney clause" of the 1958 amendment to the Food, Drug and Cosmetics Act, which prohibits the use as a food additive of any substance that "is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of food additives, to induce cancer in man or animals. . . ." The effect of this clause is to put carcinogens in a different category from that of other toxic substances. For such other substances, tolerances may be established after appropriate testing or on the basis of long experience with their use in foods. But the Delaney clause, as it has been interpreted by Secretary Flemming of the Department of Health, Education, and Welfare, sets a "zero tolerance" for any substance that can be shown to induce cancer when fed to animals in any amounts over any period of time. Opponents of the clause in the food and chemical industries, and many scientists who have no industrial axes to grind, call the clause "unworkable" and "unrealistic." They contend that the clause prevents the exercise of scientific judgment about safe levels of carcinogens in foods.

Those scientists and others who favor the Delaney clause justify putting weak carcinogens—strong carcinogens are not in question—in a special category on several grounds. Weak carcinogens usually take a long time to have an effect, and even then they induce few cancers. Furthermore, in the present state of our knowledge, it is not possible to say with absolute assurance that even a small dose of a weak carcinogen will not initiate irreversible cellular changes that may lead to the formation of cancer in man long after exposure.

For an ordinary toxic substance, the effects are rapidly manifested and are reversible. Consequently, thresholds of action for an ordinary toxic substance in animals can be readily determined, and the limit for human consumption can be set at some small fraction (1/100 or less) of the no-effect level for the most susceptible animals tested.

For a weak carcinogen, on the other hand, the long latent period and the infrequency of response make the determination of a threshold far more difficult: many more animals must be treated for much longer periods before reasonable estimates of hazards may be made. The task is difficult, but surely not impossible. What is needed is far more systematic animal experimentation with weak carcinogens, administered orally and in amounts that suffice to establish dependable dose-response relations.

These considerations and others too complex to be considered here will give the scientific panel a difficult job. We hope the panel will be able to suggest the most effective means of bringing scientific judgment to bear upon the provisions of the Delaney clause.—G.DuS.