Appendix IV

CHRONOLOGY OF EVENTS LEADING TO THE STUDY

Saccharin is a nonnutritive sweetener that was discovered in 1879 and has been in use since the turn of the century. Prior to 1972, it was classified as "generally recognized as safe" (GRAS), a classification meaning it was not considered a "food additive" for the purposes of the FDA law and therefore did not need FDA approval.

The increasing use of nonnutritive sweeteners and the widely publicized 1969 ban on cyclamates led to investigations of the carcinogenic potential of saccharin. Preliminary results of a long-term feeding study indicated formation of bladder tumors. On February 1, 1972, FDA removed saccharin from GRAS status and issued an interim food additive regulation limiting the use of saccharin in foods. FDA extended the interim regulation while awaiting a National Academy of Sciences review of the experimental data, including the two long-term feeding studies that showed bladder tumors in rats with diets of 5- and 7.5-percent saccharin. The Academy's December 1974 report stated that saccharin itself could not be identified as the cause of the tumors because of possible impurities as well as problems with experimental design and procedures. The FDA therefore continued the interim regulations while awaiting results of tests being conducted in Canada.

The Canadian study was designed to answer the objections raised in the Academy report, principally that impurities in the saccharin (specifically, a byproduct of the manufacturing process, ortho-toluenesulfonamide, or OTS) might have been the carcinogen. The Canadian study separated rats into control, saccharin, and OTS populations. The results showed that the saccharin group had an increased incidence of bladder tumors, while OTS group did not.

On March 9, 1977, FDA announced the results of the Canadian study and stated that the law required the removal of saccharin from the food supply, citing the "Delaney clause" of the Federal Food, Drug, and Cosmetic Act.

On April 14, 1977, FDA Commissioner Donald Kennedy announced the intention to propose a ban on saccharin, which was published in the Federal Register on April 15, 1977. The proposed ban would:

(1) Revoke the interim food additive regulation under which saccharin and its salts are currently permitted as ingredients in foods, thereby banning its use in foods and beverages.

(2) Allow the marketing of saccharin as a single ingredient, over-the-counter (OTC) drug.

(3) Remove saccharin from cosmetics that are likely to be ingested, such as toothpastes, mouthwashes, and lipstick.

(4) Remove saccharin as a nonmedical ingredient in drugs, e.g., when it is used to make drugs taste better.

(5) Prohibit saccharin in animal drugs and animal feeds.

On March 18, 1977, Senator Edward M. Kennedy (D-Mass.), Chairman of the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, and three other members of the subcommittee suggested that the Office of Technology Assessment convene a panel of scientists and medical specialists to study the technological basis for the FDA ruling, and to report their findings in 60 days. He also invited OTA and a group of scientists to participate in an open executive session of his subcommittee on March 24, 1977, to discuss the usefulness and feasibility of such a study, and to identify the technical and scientific issues about which more information was needed.

On March 21 and 22, 1977, the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce held oversight hearings on the FDA's proposed ban.

The Senate Subcommittee on Health and Scientific Research held the open executive session on March 24, 1977, and the invited scientists* agreed that such a study would be feasible and useful. On March 29, 1977, Senator Kennedy, Chairman of the Subcommittee, and Senator Richard S. Schweiker (R-Pa.), its ranking Republican, requested the Office of Technology Assessment to conduct the study. On March 30, 1977, the Technology Assessment Board, the Congressional body that governs OTA, approved request.

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