

## CYCLAMATES

The ban on cyclamates announced by HEW Secretary Finch in October applied to all cyclamate-containing products, including soft drinks, canned fruits and vegetables, medications, sugar substitutes and meal substitutes. Since then, the ban has been modified and now applies only to soft drinks; the other artificially sweetened products will remain available on supermarket shelves.

The original ban derived from the Delaney Amendment, which requires the removal of any food additives known to cause cancer in man or animal. At the request of HEW, a medical advisory board was asked to evaluate the benefits versus the potential dangers of cyclamates. The board concluded that for diabetics and the obese, benefits "outweigh the possibility for harm;" they recommended that cyclamate-sweetened foods, labeled and handled as drugs, be made available to those with a medical reason for use.

On November 20th, Secretary Finch lifted his original ban from all but soft drinks, stating that cyclamate-containing food and medicine — if drug-labeled — could be sold to the public without a physician's prescription. FDA and industry representatives are now deciding on the wording of the new label. Because cyclamates are now considered a drug and not a food additive, they are no longer subject to the Delaney Amendment. Whether cyclamates will undergo new-drug tests for safety and efficacy has not been announced.

An HEW spokesman maintains that Mr. Finch's change in position is not a reversal but a strengthening of the ban. In the original ruling, he said, all cyclamate products would have been available for health reasons, but with the tightened ruling, diet sodas will not be available at all.

Since the first experiments by Abbott Laboratories which showed cyclamates to be cancer-producing in rats, additional evidence of their carcinogenicity has been obtained by FDA chemist Elizabeth J. Lethco. Three of 23 rats fed cyclamates for

88 weeks as part of their regular diet developed bladder malignancies and 10 others showed pre-malignant bladder changes. The cyclamate doses were as low as 400 mg/kg, much less than the doses reported in the Abbott studies; pure cyclamates were used rather than Abbott's cyclamate-saccharin-cyclohexylamine combination, FDA pathologist Howard Richardson told THE SCIENCES.

In another study, FDA biochemist Jacqueline Verrett reports that "even at levels as low as 1/1,000th mg/kg, we still see the teratogenic effects of cyclamates." Pointing out that results from chick embryo studies cannot be directed extrapolated for man, she suggests that these findings indicate the need for further research on cyclamate safety. Dr. Verrett maintains that cyclamates would probably not pass new-drug safety tests.

*Mr. Science*  
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