The fallen hero

The recent summary ban of cyclamate by FDA raises important questions about the Delaney clause and FDA procedures

Tyranny can take a number of forms. There is, of course, the tyranny of the Hitlers and Stalins. There is the tyranny of majorities—and, we might add, minorities. There is also the tyranny of public opinion, especially in its more hysterical form, and the well-intentioned but heavy-handed government reaction to it. We think the cyclamate saga (perhaps it should be titled the fallen hero of the sweeteners) is a case in point (C&EN, Oct. 27, page 20).

If the implications were not quite so serious, the spectacle of food and soft drink producers, retailers, Madison Avenue hucksters, and others involved in the business end of the cyclamate chain falling over themselves as they try to cut loose from a product that so recently brought presumably handsome profits would be humorous, even ludicrous. As it is, the episode is tinged with overtones of Orwell and a Salem witch hunt, and, as one letter writer puts it, an "antichemical McCarthyism." Apparently, it is to be followed by more of the same in connection with monosodium glutamate, saccharin, and, who knows, table salt.

It's not that FDA has not done its duty under the law. That's precisely the problem. Secretary Finch had no choice, once presented with the facts of the matter.

We think it is time that FDA, legislators, interested technical people, and consumers at large calm down and take a hard look at the cause of it all—the so-called Delaney clause. The Delaney clause is a final provision added to the 1958 food additives amendments that prevents issuing approval or tolerance to any additive which, when ingested by man or animal, or on the basis of appropriate laboratory tests, is found to induce cancer.

That's a pretty sweeping provision. Under it, a product like cyclamate, which has not been shown to induce cancer in humans in 20 years of widespread use, can be banned strictly on the basis of unrealistically heavy dosages in animals. We think this is unreasonable and technically unsound. We think the clause should be revised or even repealed.

Few, if any, quarrel with need for careful control of products destined for human consumption, direct or indirect. The stakes are too high to leave industry and others to their own devices. Certainly it is now accepted that only the Federal Government can effectively implement the necessary controls and adequately watch over the public welfare.

But surely the Delaney clause is too broad in one sense, too narrow in another. It is too broad because it allows no tolerance. Raise dosages high enough and make test conditions severe enough and a vast number of chemicals will likely prove to be cancer inducers, even though they are perfectly safe in anything like normal use.

It is too narrow because it refers only to cancer and deals only with additives. Why only cancer? Why not cover safety in all its aspects? And why consider only additives? What about naturally occurring substances that can harm man? As it is, substances that occur naturally receive a kind of blessing, under the law as it is administered. Additives, though, can be banned, even when the hazard may be considerably less and dosages required to cause problems considerably more than is the case with natural materials.

Furthermore, we feel that FDA's operating procedures in the cyclamate case leave something to be desired. Apparently the agency was moved to action only after two of its scientists—Dr. Jacqueline Verrett and Dr. Marvin Legator—were interviewed by NBC News. Rather unusual, we'd say.

It is hoped that the coming White House Conference on Food, Nutrition, and Health (Dec. 2–4) will include some of these questions on its agenda. Meanwhile, we trust we are not starting some kind of 15-year count-down to 1984.

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