

## Controversy over New Pesticide Regulations

A controversy has flared over new regulations proposed by the Environmental Protection Agency (EPA) that could lead to more bans on existing pesticide uses than in the past and to highly rigorous screening for all new pesticides developed. The pesticide industry's concern about the proposed regulations is heightened by two recent EPA decisions. First, there was EPA Administrator Russell E. Train's decision in October to suspend most uses of aldrin and dieldrin as an "imminent hazard" (*Science*, 18 October). Now comes Train's announcement of 19 November that proceedings will be held looking to the possible cancellation of two other persistent, chlorinated hydrocarbon pesticides, heptachlor and chlordane. The pesticide industry regards these EPA decisions as similar in thrust to the Delaney amendment that requires banning any food additive found to be carcinogenic in test animals.

On 16 October, EPA published in the Federal Register its proposed regulations for the registration and classification of new pesticides, and for the reregistration of pesticides already on the market. From the manufacturers' standpoint, these regulations would pose a greater problem in the case of pesticides registered years ago than in the case of new pesticides to be registered.

Most of the pesticides that environmentalists have been worried about were registered prior to the present concern about long-term effects such as carcinogenicity. A decade or more ago, preregistration testing reflected a concern chiefly over whether a pesticide was effective for the uses proposed and whether, in the short term, it was acutely toxic and thus dangerous to applicators and others who might be exposed.

In more recent years, however, pesticide manufacturers have begun to do extensive testing for long-term effects, and, as a result, new pesticides that are proposed for registration in the future may usually prove acceptable from the standpoint of both short- and long-term effects. On the other hand, some of the "old" pesticides that will be coming up for registration every 5 years would, under the regulations now proposed, no doubt be found to pose an "unreasonable" environmental risk. In the past, reregistration has been granted more or less pro forma.

For several years now, EPA, with some goading from the Environmental Defense Fund (EDF), has been moving to restrict severely the use of some of the chlorinated hydrocarbon pesticides, which as a class are strongly suspected of being carcinogenic. DDT was the first to go, and, unless the administrator's ruling is overturned by the courts, aldrin and dieldrin also will be gone, at least for most uses. The effect of the proposed regulations would be to make for a systematic review of all old and new pesticides, not just those which for one reason or another have come under strong suspicion. The task will be vast and never ending, for the total number of pesticide formulations registered comes to 33,000.

A key provision in the proposed regulations would establish a "presumption against new or continued registration of any pesticide with extremely high acute toxicity characteristics or which produces in laboratory or field situations any evidence of oncogenicity, terato-

genicity, or multitest evidence of mutagenicity . . ." (emphasis added). The presumption would be "rebuttable," but the applicant would have to "sustain an additional affirmative burden of proof either that the risk is not so great as appears initially, or that such risk is outweighed by the . . . benefits. . . ."

The decision in the aldrin-dieldrin case is highly relevant here because, in that case, Administrator Train based his finding of an imminent hazard on conclusive evidence that these pesticides induce tumors in several strains of mice. The administrator thus affirmed the validity of using the mouse for tests to determine carcinogenicity—a point which the Shell Chemical Company, the sole manufacturer of aldrin and dieldrin, had vigorously disputed. Also, noting that tumors had occurred in mice at the lowest dosages tested, Train held that it was impossible to establish a safe level of exposure.

In its formal comments submitted to EPA, the National Agricultural Chemicals Association took particular exception to the way in which, by NACA's reading of the proposed regulations, the agency would interpret data as to chronic toxicity. NACA said that "the concept of *any* response at *any* dose . . . negates the opportunity for scientific judgment in assessment of benefit/risk."

"Recent EPA policy [decisions] give us no assurance that this 'presumption' will be 'rebuttable,' and ultimately will result in essentially all pesticide products becoming subject to unwarranted accusations," NACA said.

The controversy over the proposed regulations cannot be neatly defined as simply a dispute between, on the one hand, the pesticide industry and its allies in agriculture, and, on the other hand, EPA and its allies in the environmental movement. Within EPA itself there has been disagreement.

A strong force behind the regulations is EPA's Office of General Counsel (OGC), the unit responsible for the enforcement of pesticide regulations. Attorneys in the OGC are eager to have the agency adopt a systematic approach to pesticide evaluation.

But doubts about some aspects of the proposed regulations have arisen within EPA's Office of Pesticide Programs (OPP), although this office of course had a major part in drafting them. Those who now question the regulations are said to be found especially in OPP's registration division and criteria and evaluation division. (These divisions include many people who were transferred from the Food and Drug Administration and the Department of Agriculture when EPA, upon its creation in 1970, took over the regulation of pesticides.) Some scientists in these units are reported to sympathize with the pesticide industry's criticisms of the regulations, as in the case of the presumption against any pesticide found to induce tumors in mice or other test animals.

EPA had hoped to promulgate final regulations before the end of the year, but this now appears impossible. Where disagreements remain within the agency staff, Russell Train will have to be the ultimate arbiter, and this is all right with OGC. As one attorney there put it, "Our greatest ally is Train. The problem is to get through the bureaucratic morass."—LUTHER J. CARTER