

EPA Regulators Take on the Delaney Clause

In a challenge to the 1958 food purity law, EPA will allow small amounts of a rat carcinogen in eggs and laying hens

The Delaney clause of the Food, Drug, and Cosmetic Act says that any compound "found to induce cancer when ingested by man or animal" must be considered unsafe and banned from use in food. This famous 1958 amendment, a bugaboo of the food industry, turned up in a recent precedent-setting decision made by John Moore, head of the pesticide and toxic chemicals office at the Environmental Protection Agency (EPA). Moore seems to read the Delaney clause in a new way that renders it more flexible.

The clause is usually seen as a rock-solid prohibition against the use of any compound that would leave even a trace of a potential carcinogen in food. But in a decision involving a pesticide called Larvadex, Moore appears to see it as forbidding only significant hazards—chemicals that pose more than a negligible risk of causing cancer. Although earlier interpretations like this have failed, Moore may succeed because the new management at EPA has more public support than its predecessor and thus greater license.

"In one sense I think it represents a policy change, and a positive one," says Moore. "As issues come up which some people are going to want to scrutinize very closely, I think there's an obligation on the part of EPA to explain how it's getting to where it's proposing to go. I think this is a first good case of that." However, he does not agree that he is trying to "dance around" the requirements of the Delaney clause, as he thinks some comments recently quoted in the *Washington Post* suggested.

In notices published on 27 April, EPA announced that it intends to let chicken farmers use Larvadex, a new pesticide produced by Ciba-Geigy, in a way such that small amounts of the chemical will end up in eggs and in the flesh of chickens sold for canning. A metabolite of Larvadex, melamine, has been linked with cancer in laboratory rats. But Moore has approved the conditional registration of the pesticide through 1985, arguing that the residues appearing in food will be so small as to pose essentially no hazard.

Although Moore recognizes that Larvadex is a carcinogen at high doses for male rats, he thinks this finding has little meaning for human health. Moore also

offers a backup argument: even if the reading of the laboratory data is wrong and Larvadex is a carcinogen for humans, the public's exposure to it will be so slight as to limit the chances of its causing cancer to less than one in a million.

According to the EPA's *Federal Register* notice, Larvadex would be added at a rate of about 5 parts per million (ppm) to the feed of laying hens. The residue in chicken droppings would be potent enough to block the development of fly larvae that breed in manure, thus controlling flies in the henhouse. Broiler chickens would not be given Larvadex at all. EPA calculates that this practice would leave a residue in eggs and laying chickens (which are sent to canneries

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when they become "unproductive") of no higher than 0.25 ppm. However, EPA wants to set a tolerance level of 0.4 ppm to allow for error. EPA says that "only 47 percent of the eggs will bear residues" and only "7 percent of the chicken meat marketed annually" could be treated with the pesticide.

The bioassay of melamine written for the National Toxicology Program in 1983 reported that the chemical was not carcinogenic in mice or female rats, but did produce bladder tumors in some male rats. These rats also had bladder stones, suggesting that the tumors may not have been caused directly by the chemical but by the feeding regimen. Additional research showed a correlation between high doses of melamine and the bladder stones. As Moore explains, "The only place where one found a positive [indication of carcinogenicity] was at the high dose of one sex of one species. The general feeling is that the only reason that occurred was that the doses were so high, and there was so much melamine coming out as crystals in the urine, that the crystals aggregated in the bladder and formed stones. It was the presence

of the stones that most likely led to the tumors."

Nevertheless, to be entirely accurate, Moore says, EPA considered the other possibility—that melamine could have caused the tumors directly. When the agency did this, it called into play a complex series of Delaney precedents and exemptions. In brief, EPA decided to resurrect a proposal made by the Food and Drug Administration (FDA) in 1979 which said that feed additives may be viewed as safe if their residues do not present a cancer risk greater than one in a million.

As it happens, the residues of Larvadex in chicken and eggs would exceed the one-in-a-million cancer risk, if standard FDA dietary calculations were used. EPA got around this problem by using some new dietary calculations of its own showing that people eat much less chicken and eggs than the FDA assumes. (Rather than 33 percent of the diet, eggs and chicken make up less than 4.3 percent. With these new figures in hand, EPA concluded that even if Larvadex were a carcinogen, so little of it would be present in food that the risk of causing cancer would be infinitesimal—in any case, less than one in a million.

"We will be objecting to the whole thing," says Lawrie Mott of the Natural Resources Defense Council, an environmentalist group. She recently supervised a survey of California produce sponsored by NRDC. It found that 44 percent of the items had some pesticide residues, and that of those, 42 percent contained more than one compound. Two of the chemicals had already been banned by EPA, and several were suspected carcinogens.

Mott finds it "incredible" that the Larvadex policy is so narrowly framed and that it is scheduled to go into effect after just 30 days' public review. "It should be studied on a more generic basis than EPA seems to be doing," she says. In Mott's view, the rationale for rejecting the Delaney prohibition is based on "an elaborate theory about the bladder stones being the problem as opposed to the chemical that caused the bladder stones," a theory which she regards as clouding the issue. NRDC will ask the government to consider alternatives such as asking chicken farmers simply to sweep out their henhouses or

to spray Larvadex directly on the manure.

California may protest EPA's action as well. It is one of a score of states where Ciba-Geigy has been pushing to have Larvadex registered for use on an emergency basis. So far, the California Department of Food and Agriculture has declined. "We'd probably register it tomorrow as a spray-on" says Keith Maddy, the department's chief of toxicology. But at present, Maddy says, the

department is not persuaded that the benefits of using Larvadex as a feed-through would outweigh the risks.

Last year, Maddy says, "We proposed to EPA that they hold a national symposium on feed-through pesticides. We have questions about those already registered and about the four or five coming down the pipeline." EPA did not respond. In written comments, California may praise EPA for laying out its Larvadex decision in a straightforward

manner, according to Maddy, but it may also request a longer comment period and perhaps public hearings.

It is apparent that EPA would like to chip away at the edges of the Delaney clause. Whether the interpretation offered in the Larvadex case will be accepted or not remains to be seen. However, EPA's critics agree that the agency has earned goodwill because of the candor with which it has presented its case.

—ELIOT MARSHALL

New Directions for TVA?

With the retirement this month of Tennessee Valley Authority (TVA) director S. David Freeman, President Reagan is to announce what will be his second appointment to TVA's three-man board. The appointment is of some significance as it could influence the agency's course for the next decade on several key issues.

The most likely candidate for the 9-year term is John V. Waters, who has been promoted by Senator Howard Baker (R-Tenn.). Waters, a Tennessee businessman and former Baker campaign manager, is president of the Tennessee Bar Association, a former cochairman of the Appalachian Regional Commission, and a member of the board of the controversial Tennessee-Tombigbee stream channelization project.

Waters' emergence has aroused consternation among the members of the TVA Board Appointment Coalition, which represents 43 groups involved in environmental, economic, and social issues. The coalition has been attempting to

Myth of TVA, says the agency became a major polluter and strip miner—more than half the energy generated comes from the valley's high-sulfur coal—and resisted federal environmental laws as strenuously as any private utility. Chandler and others also argue that TVA has been plagued by inefficiency owing to its lack of accountability both to the public and the marketplace.

Freeman, appointed to the board by President Carter in 1977, succeeded in making major changes. He brought TVA into compliance with federal laws and initiated new pollution-fighting strategies. He also pushed an extensive energy conservation program which contributed to TVA's decision to cancel future nuclear power plants.

TVA has been primarily guided since 1978 by Freeman and Richard Freeman (described by the coalition as an "enlightened businessman"). The third board member and current chairman is Charles Dean, from the Knoxville utilities board, who was selected by Reagan in 1981. Dean, according to observers, is not known as an imaginative or forceful manager. Thus, the new appointment is seen as being highly significant for the future of TVA.

For many years TVA has been a paternalistic force, a major employer and focus of the valley's economy. But it appears there are limits to what economic miracles cheap power can bring about. Chandler analyzed per capita income, rural electrification, and agricultural development and found that the area using TVA power had not made any greater gains than surrounding counties. Now, say environmentalists and others, it is time for TVA to diversify and promote renewable energy technologies, new farming techniques, and other measures to stimulate grass-roots economic development.

Mohamed el-Ashry of World Resources Institute, who was director of TVA's environmental program until last year, says, "TVA has done all it can do in cheap power production. Now its reason for being should be as a national proving ground for innovative energy technologies, environmental protection, and resource management."

The future will depend in large part on the extent to which organized public opinion is allowed to affect deliberations at TVA. Board meetings were opened to the public a few years ago, but further mechanisms are needed to facilitate public participation. Educating the public is also a problem. "There is tremendous apathy in the valley," says el-Ashry. "People don't scream except when they raise the rates."—CONSTANCE HOLDEN

Some fear that public participation and environmental gains will be jeopardized by departure of David Freeman from TVA board.

influence the appointment and has tried to promote candidates it favors, including John Gibbons of the Office of Technology Assessment. Although Baker had consulted with the coalition, he did not notify it of his choice.

Jim Price, Southeast representative of the Sierra Club, says the coalition is concerned that the "fragile and tenuous" commitments to the environment and to increased public participation in TVA policies could be jeopardized with the departure of Freeman.

The federally owned TVA was established in 1933 as a massive, multipurpose, pathbreaking venture to spur the development of one of the country's most backward regions, primarily through a series of dams for cheap power, flood control, and navigation. Included in its mission was reforestation, erosion control, and promotion of fertilizer use.

Despite its early accomplishments the agency has recently come under fire from a variety of critics. For example, environmentalist William Chandler in a new book, *The*