

FDA's functions explained to farm editors

By DIETER KREIG
WASHINGTON, D.C. — Farmers are becoming more interested in the Food and Drug Administration (FDA) than they used to be, and farmers are getting to be "pretty sensitized to government actions that affect farm income," says FDA Commissioner Donald Kennedy. He made the remark Monday during a meeting with members of the Newspaper Farm Editors of America who were meeting in the nation's capital at the time.

"It seems, I suspect, to some of them that we (FDA) are joining a large group that's ganging up on them," Kennedy said early in his presentation.

"The fact of the matter is that we're perfectly well aware that FDA decisions have an impact on farm income. But the laws under which we operate don't allow us to pay much attention to that fact," the FDA commissioner explained. That means we can't take the economic losses or gains to a particular sector into account in deciding an issue of chemical safety. That's because the law explicitly doesn't let us do that," Kennedy said.

A lot of confusion surrounding FDA actions and decisions sprung up from the cloudy issues of risk-benefit and cost-benefit issues the agency is involved with, Kennedy told the group. An example, he said, is that food processors must first prove that their food additives aren't harmful if they intend to use them. This could get into decisions

which involve food packaging. A bag, for example, could release a chemical into the food, meaning that a "food additive" is added unintentionally.

To calm some of the hostility which FDA receives from the agricultural segment of society, Kennedy asked the farm editors to remember that "FDA does not ban things because they wake up one morning and think it's a nice idea. They ban it because the law says they have to. Second, you might reflect on the fact that Congress is not chosen to treat all carcinogens in the same way. The law treats them differently depending upon whether they are unavoidably present in food or whether they're put in during the course of processing or manufacturing. Those differences yield important results in the way the Food and Drug Administration carries out its regulatory responsibilities."

"I think it's important to note that even if risk-benefit calculations were possible for all the classes of compounds with which the Food and Drug Administration deals, we would have to have something to calculate ... numbers, values, something solid rather than mere assertion," Kennedy continued. "You can't divide it up so that producers get the benefits and consumers bear the risks," he explained.

To illustrate how big of a job FDA and its sister organization, the Environmental Protection Agency (EPA) have,



Donald Kennedy

Kennedy told the group that the EPA has registered some 70,000 organic compounds that are in use in this country and they're being added to at a rate of some 600 to 800 per year. Much of this boom in the use of chemicals is due to the revolution in synthetic, organic chemistry. "That's a lot of chemistry going on in the world out there, and a surprisingly big piece of it is, of course, agricultural chemistry."

Animal drugs, fertilizers, and pesticides make up the bulk of chemicals used on the farm.

Kennedy noted that FDA was a part of USDA until 1947, starting out as the Bureau of Chemistry within USDA. Now the FDA is a part of the Department of Health, Education and Welfare. Funding for FDA, however, comes from the House and

Senate Agriculture Appropriations Committee. "I want to tell you that in a year when we've had to be kind of tough on the folks involved in agricultural production, that's not the kindest and most comfortable place to go for your money." Nonetheless, Kennedy credited both the Senate and House Agriculture Committees for being "very fair minded" with their appropriations for FDA.

FDA was viewed as being in alliance with food producers in the old days, Kennedy said, but the role has changed. Agriculture has felt more pressure, despite the agency's determination to be fair to all parties.

"The worst thing to happen to any segment of the economy is the destruction of consumer confidence," the FDA commissioner said. He noted further that FDA tries to go about its duties in a way which will not discourage innovative ideas, while at the same time upholding standards which the American public expects. Those standards are inclusive of inspections of foreign produce, to insure that domestic produce is in a fair position to compete with imported produce, Kennedy said.

In conclusion, Kennedy commented: "Whenever a regulatory agency is making decisions that go tough on a particular sector of the economy, it's

very, very important for that agency to be as accountable as it can be to the people who represent the folks who are getting hurt... to the people who are getting hurt themselves so that they can ventilate those concerns and so that there is both a perception and a reality that the

government is listening. This is the purpose for the public hearings," he explained, "to be accountable to the people who are being affected by our decisions."

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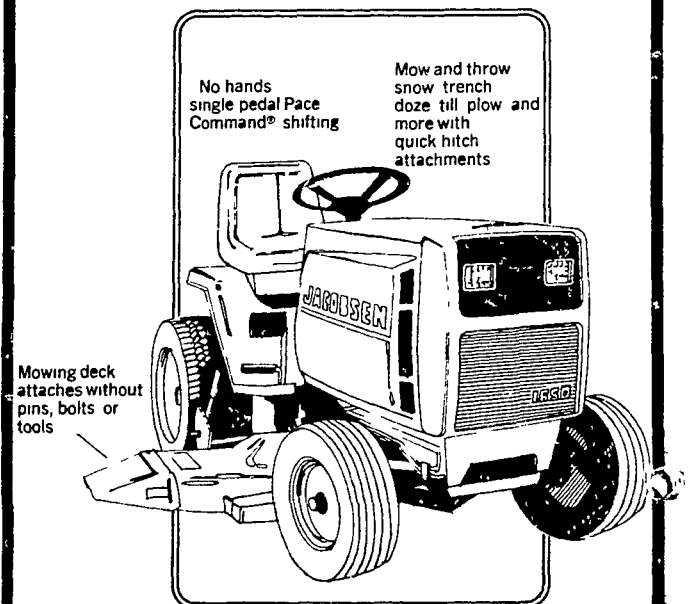
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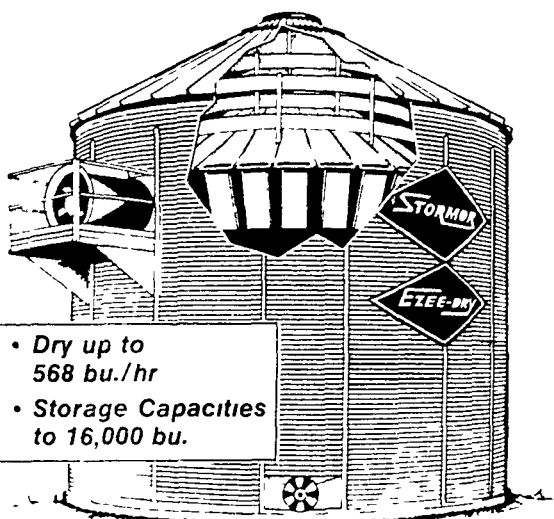
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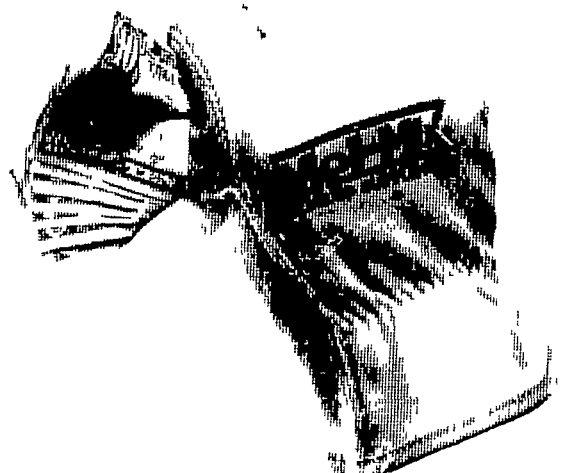
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