Reproductive Toxicity: Regs Slow to Change

A GAO report finds far too little attention is paid to toxic substances that can potentially affect the health of fetuses

THIRTY YEARS AGO, THALIDOMIDE TAUGHT doctors and regulators a grim lesson: Chemicals should be tested for their potential harm not just to those already born, but also to the unborn, before being approved for use. Since then, scientific evidence has grown that a wide range of drugs, pesticides, food additives, and other chemicals can cause birth defects, infertility, and abnormal development in children. Given those findings, you might think great strides had been made to identify and control chemical hazards to fetuses. Not so, says a report set to be released this week.

In fact, there may still be significant problems in the way the United States regulates reproductive and developmental toxicants, the General Accounting Office (GAO) concludes after 3 years of study. Its report found that regulatory agencies have not consistently applied the scientific knowledge that exists and that it is uncertain how well current regulations protect the public. Interestingly, a draft of the same report obtained by *Science* was even tougher, saying that "the pattern of regulatory gaps plus the lack of rigor in the risk assessment decisions for chemicals GAO examined suggest insufficient protection overall for reproductive hazards." The GAO said, however, that it had "backed away" from that conclusion in response to pressure from the federal agencies.

Not everyone is swallowing these conclusions. Some spokesmen for industry reject the report out of hand. "This document implies that federal agencies are just not regulating reproductive hazards, and that there are all sorts of smoking guns out there," says George Daston, a Procter & Gamble Co. toxicologist who chairs the reproductive and developmental effects subcommittee of the American Industrial Health Council. "That just is not true." And regulators at the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Consumer Product Safety Commission, and other federal agencies were busy preparing testimony earlier this week to rebut the report—primarily by documenting the cases where they have taken into account the potential reproductive effects of a pesticide, drug, or food additive. "The truth is, an awful lot of work is going on," says Victor Kimm, deputy assistant administrator for pesticides at the EPA.

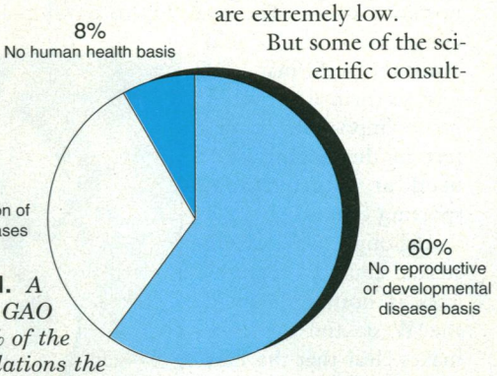
In spite of those disclaimers, the study requested by Senator John Glenn (D–OH), chairman of the governmental affairs committee, paints a bleak picture. One of the first things investigators found was that no federal agency had compiled a list of chemicals known or suspected to be human reproductive toxicants. "Federal agencies have had no index of whether they have regulated the most important hazards to reproduction and development," says the document.

As a result, GAO decided the only way it could evaluate how federal agencies were regulating these chemicals was to put together its own list with the help of 50 toxicologists, physicians, epidemiologists, geneticists, and other specialists. Thirty well-known hazardous substances made the list.

GAO found that almost all the 30 chemicals were being regulated—but largely for the risk of such things as cancer and neurological damage. In a full two-thirds of the cases, agencies did not use reproductive toxicity or early childhood development data in setting standards. In fact, even if the agencies set out to consider reproductive health, they would in many cases have to start from scratch: of more than 60,000 manmade chemicals now in use, only 4000 have been tested to see whether they harm reproduction and development in animals. "In the absence of testing, we're flying blind," says Philip J. Landrigan, a professor of occupational and environmental medicine at the Mt. Sinai School of Medicine.

Even where something is known about a chemical's potential toxicity, there is a big loophole, the report finds: Agencies regulate only some of the avenues by which people are exposed to specific substances. For example, ethylene dibromide is used in pesticides and as a solvent and fumigant, and regulations cover those kinds of uses in the field and on the job. On the other hand, the FDA has ceased to monitor ethylene dibromide in food, despite the fact that it found levels of the chemical that violate a recommended health standard in every shipment of honey sampled in 1989, the last year of monitoring. The failure to regulate chemicals in food is particularly troublesome, says the report, "since much U.S. food is imported, and foreign farmers are under no obligation to obey EPA bans" on pesticides.

Beyond arguing that much work is, in fact, going on to regulate the reproductive effects of chemicals, officials at FDA and other regulatory agencies declined to comment on the GAO study until after its release. In addition, industry toxicologist Daston said that in many cases, regulating for cancer toxicity does double duty—it should also protect the public from birth defects and environmental problems in most cases, because allowable exposure levels designed to prevent cancer are extremely low.



Flying blind. *A report by the GAO finds that 60% of the chemical regulations the agency reviewed are not based on reproductive effects.*

But some of the scientific consultants for GAO disagree, saying that exposures too low to cause cancer could still affect the fetus. "Many of us believe that reproductive and developmental endpoints are frequently the most sensitive of all toxicological endpoints," says Donald R. Mattison, a gynecologist who is dean of the Graduate School of Public Health at the University of Pittsburgh. In line with this kind of thinking, the GAO report concludes by advising Congress to require federal agencies to list reproductive hazards as a separate category and to review its current regulations on the 30 chemicals. In addition, Mattison says, the existing body of data needs to be beefed up with many more animal studies on the tens of thousands of chemicals that have not yet been tested.

In the end, what may be needed is a new approach to regulation of toxic substances. "A rational policy would be to regulate for what's the most sensitive endpoint for a particular chemical: birth defects, cancer, whatever," says Mattison. But the GAO report stops short of making such a sweeping conclusion—or estimating its cost, which is bound to be high. And in the present fiscal situation, it's unlikely Congress would be eager to foot the bill. Which could mean things will change as slowly in the next three decades as they have in the past three. ■ ANN GIBBONS