SCIENCESCOPE

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Feast or famine? FDA scientists dispute EPA dioxin report, which raises concerns about foods such as fish caught off Times Beach, Missouri.

Dioxin Report Ignites Interagency Debate

A draft report on the risks of dioxin is drawing intense fire from the Food and Drug Administration (FDA), where scientists are preparing to slam the risk assessment, prepared by the Environmental Protection Agency (EPA), as too conservative.

Last week, a key chapter in EPA's 3-year-old effort to reassess dioxin's risks to human health was leaked to the press. The draft contains several conclusions that could influence regulatory policy on the compound. One finding—that low levels of dioxin exposure may cause reproductive or immunological damage—could increase risk estimates, while another slightly diminishes dioxin's current status as a "known" human carcinogen.

These conclusions are under fire from scientists at FDA, a Department of Health and Human Services (HHS) agency. "The document overstates the risk of dioxin in many areas," says an HHS scientist involved in the review. "It departs from what we know." For instance, he says, FDA scientists question a key report assumption—that PCBs and related compounds act like dioxin. This assumption runs through the report in the form of "toxic equivalency factors," a quantification of the similarity between dioxin and other molecules that bind to the Ah receptor. "You can not find a single biological study where someone took a mixture of those compounds to check that out," the HHS scientist charges.

FDA scientists seem to be particularly concerned about the report's potential to raise alarms about the safety of meat and dairy products contaminated with trace amounts of dioxin. "The draft indicates that [dioxin] levels in food may be a problem," says Robert Lake, policy and planning director at FDA's Center for Food Safety and Applied Nutrition. "We want to be sure that's well founded," he says.

Lynn Goldman, an EPA assistant administrator and designated spokesperson on dioxin, says it's "premature" to comment on FDA's scientific concerns, which EPA expects to receive in written form in about 3 weeks.

DOE Peer Review Ruled Illegal

Peer review may be a strange concept to many federal science programs, but at the Department of Energy (DOE), the procedure is downright criminal. So says DOE's Office of General Counsel (GC), which has ruled that the peer-review process used by the agency's Office of Program Analysis violated the law on federal advisory committees.

The GC decided to investigate after receiving a complaint from Louis Ianniello, former director of DOE's Office of Basic Energy Sciences (BES), shortly before he resigned last year. Ianniello's objections date to the Bush Administration, when former Energy Research director William Happer asked for an evaluation of nearly $1 billion in BES programs—which are not usually peer reviewed—to ensure that DOE was not favoring its own labs.

Ianniello claims the reviews were wasteful, but Happer says they helped DOE justify funding requests. However, the GC ruled the reviews illegal because they produce consensus advice from outside experts, which makes them subject to advisory-panel law. That law requires such procedures as conflict-of-interest checks, which were not done in the DOE review. A spokesman says DOE has not yet decided how to respond.

A Maryland Motif for Biotech Ventures

The birth of a biotech venture on campus usually is an arms-length affair, with academic researchers standing at a distance as they pass the baton to their industry colleagues. Now the University of Maryland Biotechnology Institute has hatched a scheme to force closer collaborations: It's building a lab to house both breeds under the same roof.

The Institute plans to convert a warehouse into lab space by January 1996. The $53-million Medical Biotechnology Center (MBC) will have room for 60 geneticists, molecular biologists, and immunologists whose research it will try to market. But the info-flow won't go in just one direction: The center will also serve as an "incubator" to give scientists at start-ups cheap access to equipment and advice, says MBC director Edmund Tramont. In exchange, Maryland will collect rent and receive stock in participating firms. "What's unique about this center," he says, "is that academic and industry scientists will be rubbing elbows."

MBC is "the harbinger of the future," says Penn State economist Irwin Feller. Free from academic duties, Feller says, MBC researchers will be able to focus on interdisciplinary research. Harvard University concurs: It's building a similar facility to be completed in mid-1996.

NIH Hunkers Down for More Clinical Criticism

Clinical researchers at the National Institutes of Health (NIH) are bracing for what's likely to be a critical review, due on 2 June, of how they supervised a test of the antiviral drug fialuridine (FIAU).

Last December—after it became clear that patients under NIH care may have received toxic doses of the drug—NIH director Harold Varmus asked an outside panel to determine whether mistakes were made and, if so, how they could have been avoided. FIAU was used to treat hepatitis B infection in a study that came to an abrupt halt in June 1993 when a patient developed severe stomach pains. Subsequently, many patients suffered liver problems potentially caused by the drug; five died.

The NIH review group, chaired by David Challoner, vice president for research at the University of Florida, Gainesville, will deliver its report to Varmus at the director's open advisory meeting next month. Challoner declined to comment on the substance of the report, but he said it will take a broad view. Among the questions it aims to answer: Why was the FIAU study conducted, and how strong was the scientific basis for it? The reviewers will also judge how well NIH managed the trial and responded to early signs of toxicity.

Already, a probe by the Food and Drug Administration (FDA) has concluded that researchers should have been aware of potential toxic effects "at the start" of the study. Last week, FDA sent out "warning letters" to the two companies that sponsored the trial and the four scientists who ran it—including two senior NIH researchers—citing them for straying from the protocol and asking them to explain how they would avoid such mistakes in the future. When all their responses have been filed and the Challoner report digested, NIH will undergo a final inquiry—a review by the Office of Protection from Research Risks.