Indecision over human pesticide data

A scientific advisory subcommittee convened by the US Environmental Protection Agency (EPA), Washington DC, to study the bioethics of testing pesticides on humans, has failed to reach a consensus, delaying EPA rulings on the issue. Even if the subcommittee eventually favors accepting data from human tests, it is likely to exclude industry-sponsored research projects like those that have recently come under fire in the UK.

Under the Food Quality Protection Act passed by Congress in 1996, the EPA was required to begin re-certification of all pesticides in use in the US, including a re-evaluation of human exposure limits, by August 3rd this year. When exposure limits are based on animal models, the agency requires an additional ten-fold margin of safety to allow for species differences. Pesticide manufacturers have lobbied the EPA to accept data from human trials, which demonstrate that higher exposure levels can be tolerated. The subcommittee of bioethicists, toxicologists, and public health experts was formed in 1998 to address the ethics of testing non-therapeutic chemicals on volunteers, and was expected to issue a consensus report before the August deadline either favoring or opposing data from human testing.

Courtesy of the USDA

Nurse sprays hospital bed with 5% kerosene

Committee members contacted by *Nature Medicine* revealed that the 14-member group was split 10–4, with the majority in favor of accepting human test data. "I've been with the board 11 years. We've never had a group that could not come to some kind of a consensus, or we had a majority and the report provided a statement of the minority position as well," says Sam Rondberg, the federal official responsible for overseeing the committee, but the latter option was rejected by the subcommittee.

Bernard Weiss, a professor of environmental medicine at the University of Rochester, downplays the disagreement: "I don't think it's a really sharp division, I think it's more in the matter of tone." While the minority would refuse data from any human pesticide testing, the majority would permit such tests only when they would clearly advance scientific knowledge. "Simply undertaking human studies to revise or restore an older regulatory standard is not kosher," says Weiss.

Although the committee plans to meet again in late October to try to reach an agreement, human tests may never form a basis for US pesticide regulations because of recent high-profile cases overseas. Some chemical companies have drawn criticism for tests done in Britain, where human testing of pesticides is not illegal.

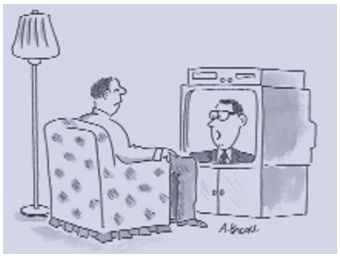
In one case, Bayer AG hired Inveresk, a company based in Edinburgh, UK, to carry out human exposure tests on azinphos methyl. Volunteers were offered £460 (US$770) and asked to swallow small doses of the compound, an organophosphate pesticide so toxic that the EPA recently established strict limits for its use on food crops. Bayer contends that its trials were carried out in accordance with international ethical and safety guidelines.

ALAN DOVE, NEW YORK

Advocates push for new NIH Office

In keeping with the American penchant for public direction of the country's biomedical research strategy, Congressional representatives Henry Waxman (D-CA) and Connie Morella (R-MD) have introduced legislation requesting the creation of a permanent Office of Autoimmune Diseases within the Office of the Director (OD) at the National Institutes of Health (NIH).

The bill, entitled "NIH Autoimmune Diseases Act of 1999" was submitted on behalf of patient groups represented largely by the American Autoimmune Related Diseases Association (AAARDA). The new Office would cost $950,000 to set up.



" Stan Hochelmeister, of the grassroots Medical Research Task Force, has successfully lobbied Congress to allocate 500 million dollars for research into a cure for Hochelmeister's disease."

There are currently over 30 offices in the OD, and the proposal appears to run contrary to the desires of NIH director Harold Varmus, who would rather consolidate the dozens of NIH institutes, offices and centers than add to them. "There shouldn't be any more independent offices unless there's a good reason," says Varmus, "…consolidation is more productive, and I am resistant to adding more administrative structures than we already have."

Last year, Congress urged the NIH to convene a coordinating committee for autoimmune disease research "to synergize research efforts among the Institutes and facilitate advances in this area." This new committee, which comprises one representative from each NIH institute, reviews NIH-funded research into autoimmune diseases such as lupus, Grave's disease, multiple sclerosis, and type I diabetes that affect an estimated 13.5 million Americans, 75 percent of which are women.

The coordinating committee will spend $30 million in FY99 promoting basic and clinical research that cuts across multiple autoimmune conditions. In addition, the collaborative network for clinical research on immune tolerance (*Nature Med.* **5**, 470; 1999) will also provide a staggering $120 million in funding to support cooperative research studies on tolerance induction in autoimmune patients. But apparently this is still not enough.

"Autoimmune diseases fall into all different Institutes, and are not the single focuses of any one Institute," complains AAARDA's executive director, Virginia Ladd. She says that the main goal of the new office will be to promote the cooperation that is currently lacking between autoimmune disease researchers from different fields, and prevent replication of research projects.

But the researchers in question are not convinced that the addition will have a large impact on their work. Stephen Straus, chief of the National Institutes of Allergy and Infectious Diseases laboratory of Clinical Investigation, says "there are advantages to having a somewhat more focused way of addressing autoimmune diseases but I don't feel that a separate NIH office would be needed to do so."

KRISTINE NOVAK, NEW YORK