

## ETHICS

## Testing Pesticides on Humans Given Qualified Endorsement

Federal regulators should be allowed to use data from controversial studies in which people are deliberately dosed with pesticides and other chemicals, an expert panel has concluded. The National Research Council (NRC) report\* says that even though some consider such tests morally wrong because they expose healthy volunteers to risks, they may be acceptable under certain conditions. The panel recommends that the Environmental Protection Agency (EPA) hold human testing to strict new standards, including review by a new agency ethics panel.

Environmental groups charged that the report is full of loopholes and urged EPA to place a moratorium on exposing humans to pesticides and other toxicants. The report's recommendations may "sound good," says Richard Wiles, senior vice president of the

\* *Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues*, books.nap.edu/catalog/10927.html

Environmental Working Group (EWG), "but that's not how they'll play out."

Pesticide makers funded human exposure studies in response to child protection rules



**Green light.** An expert panel says EPA should consider studies that expose human volunteers to pesticides.

in a 1996 law: It requires EPA to consider lowering the official safe level of pesticide exposure on the theory that children are es-

pecially vulnerable. EPA already sets levels at 1% of the safe level established by animal studies. Companies feared that an additional 10-fold reduction would be imposed to protect children, and to head this off they began sending EPA data from human testing.

EWG issued a report slamming several such studies in the United Kingdom, and EPA put a hold on using data from them. However, a 12-member advisory panel concluded, with two dissents, that certain studies should be allowed, and the Bush Administration moved to lift the hold in 2001. Activists protested, and EPA asked NRC to take a look at all human dosing studies, including those exposing volunteers to air and water pollutants (*Science*, 17 January 2003, p. 327). The stakes were raised last year when a U.S. court ordered EPA to consider the human tests on a case-by-case basis.

The NRC panel, chaired by ethicist James Childress of the University of Virginia in Charlottesville, found that these tests are not inherently unethical: Improving the science behind a regulatory decision "constitutes a societal benefit that can justify the conduct of a human ▶

## PLANETARY SCIENCE

## Look, Up in the Sky! It's a Threatening Asteroid!

It was all over in 6 hours, but the commotion triggered last month when a threatening asteroid popped up still has astronomers buzzing. The episode revealed that they have little idea how to respond when they detect an object that might hit Earth within days. "Things worked out right, but it was more or less good luck," says planetary scientist Clark Chapman of the Southwest Research Institute in Boulder, Colorado.

As Chapman explained to an impact hazard meeting on 23 February, NASA funds a search for potential civilization killers—objects 1 kilometer and larger in size—that

are almost certain to be detected years if not decades before impact (*Science*, 19 September 2003, p. 1647). The International Astronomical Union (IAU) has a formal process through which discoveries of these large near-Earth objects (NEOs) would be evaluated over the weeks and months following discovery. But "the system isn't designed to search for imminent impacts," notes Chapman.

Intended or not, an automated telescopic search first discovered a small, fast-moving NEO, now named 2004AS1, on the night of 12 to 13 January. Search operators routinely passed those observations along to IAU's Minor Planet Center (MPC) in Cambridge, Massachusetts. There staff posted a notice on a public Web page predicting where a half-dozen newly discovered objects should soon be, in the hope others could relocate them that night and refine their orbits.

A German amateur astronomer was the first to realize that the 2004AS1 predictions implied an imminent impact, news he passed to a Web chatroom. From there, a semi-retired professional astronomer passed the word to other NEO professionals, triggering a flurry of orbital calculations into the night at NASA's Jet Propulsion Laboratory

(JPL) in Pasadena, California, and back at MPC. Calculations at JPL were giving 2004AS1 a 25% chance of hitting somewhere in the Northern Hemisphere in a few days.

That was more than enough to set astronomer David Morrison of NASA's Ames Research Center in Mountain View, California, wondering, "Who do I call?" Morrison is chair of the IAU Working Group on NEOs, but this "was an event none of us was prepared for," he says. A 25% chance seemed like enough to prompt a call to somebody, though, perhaps soon. Brian Marsden, director of MPC, saw the risk differently. "There was an enormous range of possibilities depending on what you thought the uncertainties [in the observations] were," he says. "Under these circumstances, we have to be sure it's going to hit us" before calling anyone in authority. Lacking a plan, no one knew whose perception of the risk should prevail.

Late that night, a Colorado amateur astronomer averted an embarrassing false alarm by failing to find 2004AS1 on its predicted collision course. That hasn't resolved matters of NEO risk perception, but many agree with the IAU working group's 19 February statement that "the interested community should decide how cases like [2004AS1] should be handled in the future."

—RICHARD A. KERR



**Kaboom.** Asteroid 2004AS1 is probably half the size of the rock that devastated part of Siberia in 1908.

Still No Fusion for ITER

The six nations planning the \$5 billion International Thermonuclear Experimental Reactor (ITER) still can't agree on a site. A meeting in Vienna, Austria, last week failed to produce a compromise that would allow backers to select either Cadarache, France, or Rokkasho, Japan (*Science*, 13 February, p. 940). The parties intend to try again next month, when negotiators plan to take an especially close look at each site's supposed flaws. Japan, for instance, claims that Cadarache is too far from shipping ports, and Europeans warn of earthquakes in Rokkasho. Despite the high stakes, Japanese official Satoru Ohtake says the negotiations are cordial. "We don't go out drinking," he says, "but maybe we should." —DENNIS NORMILE

GM Genes Go to Seed

There's apparently no holding back the transplanted genes of genetically modified (GM) crops. A report released this week by the Union of Concerned Scientists finds that transgenes have contaminated the seeds of several U.S. staple crops. The group looked at 18 commercial non-GM varieties of corn, canola, and soybeans and found that DNA from GM crops was pervasive at low levels in many of the varieties. Overall, the report suggests that between 0.05% and 1% of this conventional seed produced each year may be contaminated. It's not known how the seeds became contaminated. The parent plants could have been exposed to GM pollen, or processors may have accidentally mixed in GM seed. The report urges the U.S. Department of Agriculture to determine the extent of contamination with a full-scale testing program, among other recommendations. —ERIK STOKSTAD

Chemists Challenge Rule

In an open challenge to the U.S. government, the American Chemical Society (ACS) last week lifted its ban on papers submitted to ACS journals from countries under a U.S. trade embargo. The society instituted the ban last November following a ruling by the Office of Foreign Assets Control (OFAC) that journals need a license to edit submissions from Iran, Sudan, Libya, and Cuba (*Science*, 5 December 2003, p. 1639). ACS decided to go back to "business as usual" after "concluding that the OFAC ruling was a violation of the First Amendment," says Robert Bovenschulte, head of the society's publishing division. ACS will "absolutely not seek a license," he adds. The Institute of Electrical and Electronics Engineers and the American Society for Microbiology, meanwhile, have applied for a license but have not yet received one. —YUDHIJIT BHATTACHARJEE

dosing study," the report says. EPA should accept such data, however, only if they are scientifically valid, the information can't be obtained in other ways, and even private studies comply with federal ethical standards known as the Common Rule.

In addition, one kind of test—feeding chemicals to people to reduce the uncertainty in animal data—should be accepted only if subjects will experience no harmful effects, the report concludes. In general, this would allow metabolism studies in which volunteers are given tiny doses that cause no symptoms but result in changes in enzyme activity that can be detected in blood or urine.

The report recommends creating guidelines and a strict approval process, however.

It says EPA, which now has no ethics board of its own, should set up a Human Studies Review Board to offer companies advice before they sponsor a study and help EPA decide which studies to accept.

As for the 19 pesticide tests already submitted to EPA, many of them metabolism studies, they could be used, the report says, if they are found to meet the report's standards. According to Patrick Donnelly of the pesticides group CropLife America, which praised the NRC report, "they all will [meet the standards]." But toxicologist Jennifer Sass of the Natural Resources Defense Council disagrees. She examined several and says, "None of them has any [scientific] validity."

—JOCELYN KAISER

SARS TREATMENT

Interferon Shows Promise in Monkeys

During last year's outbreak of the deadly respiratory disease SARS, doctors tried all kinds of treatments, from antiviral drugs and antibiotics to compounds that slow down or jazz up the immune system to traditional Chinese medicine. Many think some of these may have done more harm than good. But during the emergency, researchers were unable to set up rigorous clinical trials that could have separated wheat from chaff.

Now, a team led by Albert Osterhaus at Erasmus University in Rotterdam, the Netherlands, reports the first animal evidence that a well-known antiviral drug called interferon- $\alpha$  may work against SARS—if given in time. Interferon- $\alpha$  is already registered as a drug for the treatment of hepatitis C and several cancers; a trial in human patients could start almost immediately if SARS were to return.

Eager to do something—anything—for their SARS patients, doctors early on started treating them with an antiviral drug, ribavirin, as well as with steroids, which dampen the immune response and are often used in other pulmonary infections. The combination quickly became the standard of care in many countries. But although some studies suggested that patients responded well, "they lacked robustness to draw firm conclusions," says Simon Mardel, a medical officer working on SARS at the World Health Organization (WHO) in Geneva, who lauds the Rotterdam study.

Interferon- $\alpha$ , which comes in more than a dozen different varieties with different poten-

cies, not only blocks the replication of several viruses but also activates the immune system. It was first tried in some 30 of the earliest patients in the Chinese province of Guangdong but appeared ineffective, a group of Chinese researchers reported recently in the *Journal of Medical Microbiology*. A small trial in Toronto, published in December in the *Journal of the American Medical Association*, suggested some benefit. In that study, nine patients re-



Lifesaver? A small trial during the Toronto outbreak first suggested that interferon- $\alpha$  helped SARS patients.

ceived a different version, called alfacon-1, in addition to corticosteroids, while 13 did not.

In the Rotterdam study, published online this week in *Nature Medicine*, cynomolgus macaques that were given so-called pegylated interferon- $\alpha$  (a form designed to last longer in the bloodstream) 3 days before infection with the SARS virus excreted far less virus from their throats, and their lung damage was reduced by some 80%. When the animals were given the compound 1 and 3 days after exposure, lung damage was also reduced, ▶

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