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US crackdown on bioterror is backfiring

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19:00 05 November 2003

Exclusive from New Scientist Print Edition

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This week, a respected biologist was led into a Texas courtroom. He faces no fewer than 68 charges and could end up in jail for the rest of his life. Has the FBI finally caught the anthrax attacker?

No. Thomas Butler merely reported that 30 vials of plague bacteria had gone missing from his laboratory at Texas Tech University in Lubbock. Many of Butler's colleagues believe the justice authorities are making an example of him as part of a wider effort to ensure that scientists take more care with material terrorists might exploit.

Whatever the outcome of the case, that effort is having repercussions that go far beyond the fate of one scientist. **New Scientist** has contacted more than 20 prominent figures in the US working in bioterror-related fields.

Some refused to talk, and most who did did not want to be named. Their comments paint a disturbing picture. Some scientists, for instance, are refusing to work on projects involving agents that could be exploited as bioweapons, even though the US government is providing massive funding to boost such research.

Others are considering abandoning existing work. Irreplaceable collections of microbes essential for managing and tracing outbreaks, bioterrorist or natural, are being destroyed simply because labs cannot comply with the new rules.

Cell mate

The climate of fear created by the Butler case is even threatening the US's ability to detect bioterrorist activity. **New Scientist** has been told that labs in one state are no longer reporting routine incidents of animals poisoned with ricin, a deadly toxin found in castor beans, for fear of federal investigation.

And if any terrorist ever does make off with dangerous bacteria, it will be a brave scientist who tells the FBI. As one put it: "I don't want to end up in a cell with Tom Butler."

In a letter sent to the US attorney-general John Ashcroft in September, Stanley Falkow, a respected researcher at Stanford University in California, goes further: "Trying to meet the unwarranted burden of what the government considers 'biosafety' is simply not coincident with the practice of sound, creative scientific research."

It is now two years since someone killed five people and created widespread disruption by posting envelopes of anthrax around the US. Coming just weeks after 9/11, the attacks shone a glaring spotlight on the risks of disease research.

The authorities decided far tighter control was needed over biologists with access to dangerous pathogens. Their main response was 2002's Bioterrorism Preparedness and Response Act, which from February 2003 imposed tight controls on "select agents", a list of 82 viruses, bacteria and

toxins that could be used as weapons.

The list includes the agents responsible for many significant diseases that affect people, livestock or plants, including foot and mouth disease and the BSE prion that causes mad cow disease. Even botulinum toxin is on the list, though the medical version, Botox, is exempt from the regulations.

Fingerprint records

People working with select agents now have to register with the government, put their fingerprints on record, get security clearances, and have their labs inspected. Extensive controls have been placed on the movement of microbes and researchers, and all samples of select agents must be strictly accounted for or destroyed.

There were controls on transporting some microbes before, but now possessing them is also regulated, and non-compliance is a crime. The scientific community does support tighter controls, says Ron Atlas, former president of the American Society for Microbiology (ASM).

"Common sense as well as government regulations dictate that the days of carrying vials of dangerous pathogens in our pockets are gone, as are those of leaving cultures of anthrax in open laboratories," he says. "As scientists we must honour a pact with the public to protect public health and defend against bioterrorism."

The ASM, together with leading journals such as *Nature* and *Science*, announced in 2002 a voluntary self-censorship code that requires crucial details that could be exploited by bioterrorists to be removed from scientific papers.

But the regulations the US government has brought in, and the way they are being implemented, are driving some scientists to despair. For example, the Centers for Disease Control in Atlanta must now give permission to work with human pathogens, while the US Department of Agriculture manages livestock diseases.

This ought to allow diseases such as anthrax that affect both people and animals to be dealt with by either agency. But in practice, some say, one agency will tell researchers they do not have the right paperwork, even if the other gave them clearance.

Search and destroy

Other rules are simply badly thought out or inconsistent. One part of the regulations states that clinical labs that grow new cultures of select agents must destroy them within seven days, one researcher complains. But another part requires labs to get permission before destroying any cultures - and this takes more than seven days.

Such problems leave scientists feeling that compliance is simply impossible. "Every single lab involved in select agents has violated the regulations somehow," says one. "The FBI can come in and find you out of compliance whenever it chooses."

The implications for government control of what scientists can do or say is, in the words of one, "McCarthy-esque". Even when the rules are clear, complying with them can be prohibitively expensive. One state university had to hire five full-time police and an extra secretary just for three moderately sized labs. Institutions that cannot afford this are giving up research involving select agents.

One researcher, again afraid to be quoted, had to drop a proposal for work on ricin because it required a collaborator with particular equipment. "None would work on a select agent without millions of dollars of government money, prepaid," the researcher says. On top of the financial burden, potential partners do not want to risk criminal liability if they accidentally break any rules.

Meanwhile, researchers who have not been able to meet deadlines for registering every single sample of select agents they hold are having to destroy them. Many labs have thousands of samples, and such collections are important for diagnosis, drug and vaccine testing, and for tracing outbreaks. After the 2001 anthrax attacks, for instance, one collection helped investigators to identify the strain used.

"All clinical labs in this country have now dropped select agents and destroyed their archive stocks," says one prominent researcher. Scientists at big government labs say that smaller institutions are appealing to them to take their collections. "We haven't been able to save nearly enough," says one. And the bureaucrats "are not helping".

Even military labs are not immune. "I have had to autoclave three freezers of Venezuelan equine encephalitis," says Peter Jahrling of the US Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland, because regulators had wanted a full account of each sample by a deadline he could not meet.

The disease, which can kill people and animals, is considered a prime bioweapon candidate, but it is also endemic in many countries in the Americas and USAMRIID is working on a vaccine.

Lock out

Until last week many researchers faced the prospect of being excluded from their own labs, because after 12 November only people who had passed an extensive government background check were to be allowed access to select agents.

Partly because of initial understaffing, the FBI has not yet approved many staff. Even government scientists who already have high-level security clearances must get new ones to continue working in their own labs, and yet more to visit collaborators.

The deadline was extended last week only after desperate appeals from four university associations and the American Society for Microbiology. Those who have sent in complete applications by 12 November will now have provisional approval. But the FBI has yet to receive complete applications from 2000 of the 9000 researchers listed as needing clearance.

Part of the problem was that the FBI sent out the forms late, and there has been confusion over the exact requirements. Many of the difficulties seem to be teething problems resulting from the introduction of a new security culture to scientists whose work has in the past been largely unregulated, and doing it within very tight deadlines.

But the damage could be permanent. If the current trends continue, many scientists will not be willing to do research that could help protect people - in the US and elsewhere - against natural disease outbreaks or deliberate attacks involving the select agents.

"How could I possibly permit my students and myself to be subject to the same nightmare [as Butler] if we also made an inadvertent mistake?" asks Falkow in his letter to Ashcroft. "I know this fearful feeling is true not only of American scientists but also of colleagues from abroad... You have your regulations but I believe you will have fewer knowledgeable scientific practitioners of infectious diseases research."

"If I am required to inventory every vial, even if it is in a locked freezer behind five layers of security, then be held criminally accountable for any mysterious disappearance when it is almost certainly only sloppy record keeping," says another researcher, "then I'll work on *Paramecium* [a pond protist] and leave the select agents to someone else."

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Printed on Wed Jun 15 05:27:25 BST 2005