

New regulations proposed

Washington

NEW federal proposals to regulate the care and use of animals in laboratory experiments have outraged the US biomedical research community, prompting more than 5,000 written complaints to the Department of Agriculture Animal and Plant Health Inspectorate Service (APHIS).

The proposed regulations are described as useless, time consuming and expensive. APHIS is accused of misinterpreting the statute from which the regulations stem and is urged to scrap its proposals and start again. But animal-rights groups, which galvanized 2,000 responses from members of the public, complain that the regulations are not tight enough.

By contrast with the existing animal-welfare policies of the Public Health Service (PHS) and the National Institutes of Health (NIH), APHIS proposes minimum required standards for the design of laboratories and experiments involving animals. These include regulation of the temperature, humidity and lighting of enclosures; a requirement that dogs must be able to see and hear other dogs and must be released once a day for exercise for a period of 30 minutes; and regulations to improve the "psychological well-being" of non-human primates.

Researchers agree that new animal-welfare regulations are needed to ensure compliance with existing guidelines but are opposed to the imposition of rigid and arbitrary design standards by an outside agency. Under the existing policies, institutions determine how the recommended standards are met. By proposing regulations which conflict with the approach of the NIH and the PHS, the Department of Agriculture is accused of exerting more authority than it was granted by Congress under the 1985 Animal Welfare Act amendments. John Miller, of the NIH Office for the Protection from Research Risks, says the NIH is trying to convince APHIS to adopt an approach in line with their own. They have had some success and the policies agreed so far are similar to existing ones, he said.

The Humane Society of the United States welcomes the proposed regulations. Martin Stephens, director of the group's Laboratory Animals Department, says that "in an ideal world, performance standards would be better than design standards, but it would be very difficult to ensure adherence to them". But he argues that there are too many loopholes in the regulations and says that some may have little impact on animal welfare. The exclusion of birds, mice and rats from the regulation would cause "a serious outcry" from the public, he said. APHIS says it is considering regulations to include them.

Under the new regulations, most research institutes would have to renovate or replace cages and equipment and construct new housing facilities to meet increased space requirements, but no money has been appropriated by Congress to cover the costs. APHIS estimates the necessary capital expenditure to be almost \$900 million and maintains that since current spending on biomedical research is more than \$12.8 billion per year, the community can afford the increased costs.

But the Pharmaceutical Manufacturers Association (PMA) says that for its members alone the new regulations would cost \$345 million and that the APHIS estimate is several times too low. The PMA also complains that the regulations would "entangle researchers in a web of unnecessary paper" and that delays in the drug approval process could add millions of dollars to the research and development costs for each successful drug approval by the Federal Drug Administration. The American Association of Medical Colleges says the effects of the regulations could be "devastating" and some institutions will have to cut back their research programmes considerably. Others complain that such restrictive regulation of research will drive researchers to other countries.

The reporting and record-keeping requirements of the new regulations are extensive. For example, before any research which might involve pain in an animal is carried out, the principal investigator must provide a written assurance that alternative procedures were considered and found to be unsuitable, describing what they were, and also providing assurances that the experiment does not unnecessarily duplicate previous experiments.

Under the new regulations, the location of facilities where animals are housed or used in research must be revealed in the institute's annual report. Researchers say that animal activists will have access to the information and security will be jeopardized, thus increasing costs still further. They also complain that APHIS inspectors will be allowed to make copies of records and take photographs. This could lead to the public revelation of trade secrets.

The regulations for the "psychological well-being" of non-human primates have been strongly criticized. Researchers say forcing primates into groups would be traumatic for the animals and dangerous to humans. Field biologists are urging APHIS to exclude wild animals from the regulations, urging that the mandatory twice-yearly inspections will be logistically impossible.

Christine McGourty

Cambridge law passes unanimously

Boston

THE Cambridge (Massachusetts) City Council has ended, at least for the time being, a three-year battle between local research scientists and animal welfare advocates by passing unanimously the nation's first city ordinance to protect laboratory animals. As expected, the vote, taken at the end of June, establishes a "Commissioner of Laboratory Animals", who will have the right to conduct surprise inspections of research facilities within the Cambridge city limits which use animals.

Also as expected, the new law requires all research institutions in the city — including commercial laboratories — to conform to federal statutes and regulations concerning the care of laboratory animals and expands those regulations to include rodents, birds, fish, reptiles and amphibians which are at the moment exempted from the federal Animal Welfare Act. And finally, the law requires all research institutions to create autonomous animal-care committees — with the power to disapprove or restrict experiments — whose membership must include one public member subject to city approval (see *Nature* 339, 496; 15 June 1989).

But the council rejected a key amendment that would have required the presence of an animal-rights advocate on each research institution's animal-care committee. Of all the provisions under consideration, this was the one most vociferously resisted by the research community. David Nathan, chief physician at Children's Hospital and president of the research-orientated group Citizens United for Research and Education, says "the council was wise enough to see that individuals who are morally opposed to any animal research cannot possibly regulate its quality".

Animal-rights supporters saw a victory in the precedent set by the new law and because of the size of the animal population affected. Cambridge, a city with one of the highest concentrations of research laboratories in the United States, is home to thirteen large research institutions which in total use an estimated 60,000 animals a year.

But researchers in the city say that they can live with the city council's decision. Richard Taylor, professor of biology at Harvard University and head of its animal care committee says that researchers are doing "an absolutely first-rate job" and can withstand "any level of scrutiny". According to Taylor, the research community would not tolerate "somebody who's philosophically opposed to research on our committee who could stop the research". After the vote, Taylor spoke for many researchers when he said "it could have been a lot worse".

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