Animals aren't drugs

The US Food and Drug Administration is misguided in its approach to genetically modified animals.

It is more than 25 years since Ralph Brinster and Richard Palmiter first developed genetically engineered (GE) mice, proving that recombinant DNA techniques could be used to engineer animals. It has taken the US Food and Drug Administration (FDA) nearly as long to develop guidelines laying out its regulatory approach to such animals, be they intended as pets, as living drug factories or to supply American dinner tables.

In September, the FDA finally delivered its draft guidelines, effectively laying out a detailed playbook for companies seeking the agency's seal of approval to bring to market everything from fast-growing salmon to pigs with livers engineered for human transplant. The period for public comment on this important FDA document ends on 18 November (see http://www.fda.gov/cvm/GEAnimals.htm).

It is high time that the FDA stepped in to regulate this field, in which companies such as Aqua Bounty Technologies, a small Massachusetts enterprise that has engineered a salmon that grows to marketable adult weight in 18 months instead of 30, have been undermined by the agency's slowness to act. Agency involvement will, furthermore, bring needed regulatory oversight to an enterprise that, although often promising, could in individual instances go awry with unhappy and unpredictable consequences for the animals, public health and the environment.

But the agency's regulatory approach to the issue is troubling. It has used an eyebrow-raising reading of the 1938 Federal Food, Drug and Cosmetic Act to assert its regulatory authority over GE animals. The FDA says, in effect, that these animals meet the definition of a 'drug' under the law because they contain DNA that is "intended to affect the structure or function of the body." Following from this, the guidance says that every new GE animal — with the notable exception of lab animals used in research — will be regulated as if it contains a new drug.

When a conventional drug is being assessed by the FDA, the existence and details of the application are protected under law from public scrutiny. Such protections are necessary in the highly competitive world of human pharmaceuticals. Applied to GE animals, they are much less appropriate. In essence, the agency is saying to the public 'trust us' — in the absence of evidence, for example, that it is adequately equipped to assess the potential environmental impacts of such animals. It is not just environmentalists who are raising the red flag; the National Research Council, in a 2002 report on animal biotechnology, listed "novel environmental issues" and the technological capacities of agencies like the FDA as among its "major concerns".

It is understandable that the agency is trying to pour new wine into the 70-year-old wineskin of the federal drug law; the law is the only tool at its disposal for regulating GE animals. But as Henry Miller of the Hoover Institution at Stanford University, California, noted in a recent correspondence in *Nature Biotechnology*, "When the only tool you have is a hammer, more and more problems begin to look like nails." (See http://www.nature.com/nbt/journal/v26/n2/full/nbt0208-159.html.)

More light on the process than the FDA's proposal allows is needed to build public trust and to ensure that all necessary steps are taken to avoid adverse events. The current law cannot do this. Congress should step in and produce one that does. ■

Scientists and rights

Researchers should support new initiatives aimed at engaging them with human-rights groups.

Six foreign medics escaped the Libyan death penalty last year thanks to intense diplomacy, supported by the advocacy and decisive expertise of scientists. But the researchers' involvement was largely a matter of luck and serendipity. Science and scientists have much untapped potential to contribute to human-rights issues, but until now there have been limited efforts to systematically consolidate the interactions between science and human-rights groups. Two new initiatives of the Science and Human Rights Program of the American Association for the Advancement of Science are intended to help fill that gap.

Its "On-call" Scientists program launched last month aims to create a database of scientists who will volunteer time — be it a few days or a few months — and expertise, and human-rights organizations — including non-governmental organizations and international agencies such as the United Nations — seeking practical help or advice. (See http://oncallscientists.aaas.org/default.aspx.)

'Human rights' covers a gamut of issues, from exposing abuses to disaster relief. The range of scientific advice sought is correspondingly broad — statistical or methodological help to get a more accurate picture of conflict or ethnic cleansing, advice on water issues from hydrologists, or forensic help to document mass executions or overturn false convictions.

The service faces a steep learning curve in deciphering the diverse needs of human-rights groups, and how scientists might be able to help in ways perhaps not yet imagined. But better communication between scientists and the alphabet soup of human-rights groups — and between those groups themselves on technical issues — is long overdue.

Another welcome initiative is due in January 2009. Many learned societies, as well as academic groups such as Scholars at Risk, have a long history in upholding human rights and academic freedom — for example, defending scientists under threat from oppressive governments, using satellite imagery to expose human-rights abuses and speaking out on abuse wherever it occurs. To put such efforts on a firmer footing, American organizations are to launch the US Science and Human Rights Coalition, a forum in which scientific bodies and human-rights groups can share experiences and best practice. Given the US presidential election, the timing could not be better. For the past eight years, American human-rights groups have seen their international influence undermined by the US administration's diminishing moral authority and standing in the world. Scientists can, and should, help reinstate the fundamental principles enshrined in the Universal Declaration of Human Rights in 1948. ■