IN brief

EU tightens animal rules

The European Commission has published plans to reform its current animal-welfare directive. The draft proposal has drawn criticism from industry groups who say the new rules will merely lead to increased bureaucracy without commensurate benefits for animal welfare. The revised directive is aimed at strengthening protection for animals used in research and would address the differing standards across member states. Besides banning the use of great apes, the new provisions would require increased cage sizes and rigorous ethical evaluations to be carried out before projects using animals are authorized. There are concerns, however, that implementing such changes will disproportionately burden small and medium-sized companies, and may push animal research out to countries with lower standards, such as China and India. Simon Festing, executive director of the Research Defence Society, a London-based organization that represents scientists using animals for medical research, says the directive is exceptionally disappointing. He thinks it is unlikely to achieve the goal of improved animal welfare and could threaten burgeoning biotech in the EU. "Countries that are not paying sufficient attention to these changes risk strangling a potential biotechnology sector in the future," says Festing. "It seems to us extremely shortsighted of countries like Poland and the Czech Republic to say that they're not too bothered because they don't have that much biotechnology." The new provisions will be debated for at least a year before they become law. *—Hayley Birch*

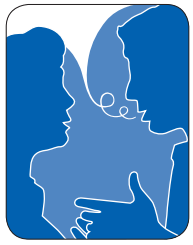
Public life cut short

Bioheart, the single biotech to go public this year in North America, faces delisting eight months after going public. The Sunrise, Florida–based company is expected to appeal the NASDAQ staff determination notice received on November 17, threatening to suspend trading and remove the company's securities. "There has been a sharp increase in delistings as most companies fail to find a healthy financing window," says Cowen and Company senior research analyst Phil Nadeau. Bioheart's troubles surfaced in October, when the company received a delisting notice for falling below NASDAQ's $35 million market capitalization minimum. The company filed for IPO last February and expected to raise $35–47 million, but instead brought in $5.8 million at $5.25 per share after lowering its initial public offering price range from the original $14–16. The company, which is burning through about $4 million per quarter and has $3 million in total assets, is in need of cash. Like other public biotech firms in this economic downturn, it might be forced to look outside the public markets. "In the current risk-averse environment, nonprofitable small and micro-cap biotechs will be adopting alternative financing vehicles more common in other sectors, such as venture debt or selling royalty streams," says Nadeau. Bioheart's product portfolio includes Myocell, the autologous stem cell therapy for heart failure patients in phase 2/3. *—Victor Bethencourt*

Pfizer's $100 million stem cell stake

Pfizer has launched Pfizer Regenerative Medicine, an independent research unit focused exclusively on using stem cells to develop new medicines. The New York–based company will spend more than $100 million over the next 3–5 years on the new initiative, which will employ 70 researchers based at two facilities, in Cambridge, Massachusetts, and Cambridge, UK. The UK group will focus on neural and sensory disorders, whereas the US team will concentrate on endocrine and cardiac research. In-house researchers will work with both embryonic and adult stem cells, but significant collaborations are also planned. Chief Scientific Officer Ruth McKernan, who will head the UK site, says: "We are keen to take advantage of successful work done by other companies and academic labs. We will be working with several collaborators and these will be announced in the new year." In the past, big pharma has shied away from investing in stem cell research, but Pfizer's move confirms that attitudes are changing. London's GlaxoSmithKline recently signed a $25 million four-year deal with Harvard University, and the venture funds of Basel-based Novartis and Roche helped bankroll Cellerix, a Madrid company testing stem cells from fat to treat rare skin conditions. Stanford University, California, also recently announced the construction of the world's largest stem cell research building to house over 600 scientists by 2010. *—Nayanah Siva*

IN their words



"The agency is hanging on by its fingertips in protecting us."
William K. Hubbard, a 27-year veteran of the Food and Drug Administration, comments on the need to boost agency funding so that it can keep apace with its responsibilities.

"An opportunity to sell new versions of snake oil."
Theodore Friedmann, director of the University of California-San Diego Medical Center's interdepartmental gene therapy program, describes Atlas Sports Genetics' ACTN3 genetic testing kit touted for predicting "speed, power and endurance" (*NY Times*, November 30, 2008).

loans for farmers. All of these vulnerabilities were exacerbated by the unscrupulous selling of counterfeit seeds, which often contained a mix of transgenic and conventional hybrids.

Crop failures were seized on by activist groups in India, such as Gene Campaign, which had previously campaigned against—and indeed successfully delayed—the commercial rollout of *Bt* cotton. "The statements they made weren't completely wrong, but they weren't completely representative," says Qaim, who says his own work in India is in agreement with the IFPRI findings. The evidence for the scale of *Bt* crop failures is anecdotal, as is any causal connection with farmer suicide. Where such failures did occur, the IFPRI report blames the conditions in which the technology "was introduced, sold, and used" rather than the technology itself.

Vandana Shiva, the country's most prominent anti-biotech activist, rejects this line of reasoning. "You cannot separate the technology from the context. That doesn't work at all," she says. Any seed that is sold to a farmer, she says, is sold on the basis that it will work for them within their specific ecological and socioeconomic contexts. She is critical of the overall report, moreover, including its failure to deal with what she sees as the real underlying problem. "Nothing in that paper is addressing the issue of debt, which is the prime cause of suicide," she says.

Morse, who is a geographer (some of whose work in India has been funded by St. Louis-based Monsanto), says the experience with *Bt* cotton in that country is broadly similar to the introduction of *Bt* cotton in the Makhathini Flats, in KwaZulu Natal Province in South Africa, where he has also performed field research (*Nat. Biotechnol.* **22**, 379–380, 2004). He also sees parallels between the introduction of *Bt* cotton in India and an unsuccessful attempt to introduce conventional hybrid varieties of maize in Nigeria during the mid-1980s. "The same issues frankly have always been there," he says. Farmers take time to adapt to new varieties and conduct small-scale experimental plantings as part of their learning process. "Farmers have done this for centuries," he says. "The GM varieties are no different, I think, in terms of that basic dynamic."

The clash between an ecological approach to agriculture and one based on biotech remains, of course, at the heart of the exhaustive and circular debate on transgenic crops. Matin Qaim says it is a "pity" that no one has found a constructive way of adopting the two. "In my eyes both are important approaches. They're not actually mutually exclusive."

Cormac Sheridan *Dublin*