nature biotechnology
VOLUME 19 FEBRUARY 2001

Flags in the wind

Biotechnology policymakers the world over often seem to be walking a tightrope narrower than the margin of a Florida ballot. With the ceremonies (such as they were) of the last US presidential election finally concluded, President Bush must now face the really difficult (some would say impossible) task of doing some deep thinking, as well as some political tiptoeing, around a variety of issues, including biotechnology.

Make no mistake, Bush's first appointments to the cabinet augur well for rational biotechnology policy (p. 97). The replacement of USDA current secretary Dan Glickman (who last year acquiesced to public pressure to prohibit GM crops from organic food) with Ann Veneman promises regulatory oversight based on—wait for it—sound scientific principles. Veneman, a former director of Calgene, served for 13 years as deputy secretary of agriculture in the Reagan and Bush Sr. administrations. She was involved in the original US legislation regulating GM products on the basis of substantial equivalence.

The replacement of US Environmental Protection Agency administrator Carol Browner with New Jersey Governor Christie Whitman is also welcome. Under Browner, EPA continued to promulgate a whole raft of tortuous regulatory requirements for field-testing biotechnology products, consistently ignoring scientific consensus on risk assessment of transgenic crops.

Wisconsin Governor Tommy Thompson's appointment as head of the Department of Health and Human Services also is promising. Thompson, a major advocate of the biotechnology industry in his home state, is familiar with drug pricing issues, is bullish about investment in biomedical research, and despite strident opposition to abortion, views stem cells as a "groundbreaking development". He is likely to have a large say in the appointments of the director of the NIH (currently Ruth Kirschstein) and the commissioner of the US Food & Drug Administration (currently Jane Henney), both yet to be announced.

Federal funding for biotechnology research also appears safe. Unlike his father, George W. has already pledged big increases in spending for biomedical research. Hopefully, he will continue the trend of increased funding for the US National Institutes of Health ($2 billion in 1999 and 2000, respectively), part of Congress's five-year plan to double the NIH budget.

But will stem cell research be part of that funding increase? At the moment that may be a distant hope, as Bush is opposed to "federally funded research for experimentation on embryonic stem cells that requires live human embryos to be discarded or destroyed." Indeed, there is a danger that the conservative right and antiabortion activists will persuade Bush to appoint an NIH director completely opposed to stem cell research.

The policy on stem cells is particularly troubling, not least because stem cell research is only one of many areas of biotechnology research that challenge the status quo and threaten traditional attitudes to "the natural order" that are held so dearly by conservatives.

Indeed, if the US president needs evidence as to the dangers of muddled biotechnology policy, he need look no farther than Europe (that's the continent directly east of the United States, George) and the EU summit meeting in Nice last December, where once again biotechnology policy was three sheets to the wind.

European biotechnology legislation has long used Directive 90/220 to bring approval of all released GM products within the purview of European officials and national ministers concerned with the environment. Officials with other briefs have additional legislation to dig certain products—vaccines and food, for instance—out from under the environmental legislation. And recently, officials concerned with agriculture have limply attempted to smuggle GM grapevines beyond the environmental power base. To sum up, envirocrats have obfuscated and environmental ministers have delayed as many GM product approvals as possible. More than a dozen GM crops are in regulatory limbo as a result.

Ordinarily, such discouragement would dry up a product supply. The need for environmental legislators would evaporate. But there are other European officials whose job it is to encourage the development of new products. These people administer the R&D funds of the European Union. Their latest coup, shared with US and Japanese officials, was the completion of the sequencing and analysis of the first plant genome, that of *Arabidopsis thaliana,* a feat reported in *Nature* in mid-December. The same group of European R&D officials is behind moves to encourage the development of small entrepreneurial biotechnology companies.

Thus, it seems that while one set of officials nurtures fluffy and hopeful biotech chicks, another roasts them to leathery nothingness in a tortuously slow regulatory oven.

Europe's national leaders clearly want this dualistic futility to continue. The pre-Treaty text from the Nice summit, on the one hand, encourages the continued construction of a "European Area of Research and Innovation" and calls for measures to increase the attractiveness of scientific careers (article 26). The European Commission has already committed substantial funds to exploring the function of *Arabidopsis* genes.

At the same time, it calls for expanding opportunities for blocking the approval of GM plants. That would be the effect of implementing Annex III of the prototype Treaty of Nice, which deals with the precautionary principle. Annex III asks the Commission and the national authorities of the EU member states to push the precautionary principle "in the relevant international health, environment and world trade for a. . .particularly at the [World Trade Organization]." It asks the European Commission to "incorporate the precautionary principle, wherever necessary, in drawing up its legislative proposals and in all its actions" (paragraph 24 of the Annex) although it seems to recognize that there will be regulatory mayhem as a result: "owing to insufficient data and the nature or urgency of the risk, [paragraph 8 says] it may not always be possible to complete every stage systematically."

Sometimes flags are used as semaphores. If this is the case for biotechnology policy, why is it so difficult to decipher the message contained in the waving banners of the different political players? After all, wasn't this meant to be the global age when everyone spoke the same language? ///