several federal agencies including USDA is problematic and questions whether this system will measure up when it is asked to inspire public confidence and provide the scientific community with adequate guidance.

Val Giddings, vice president of agriculture for the Biotechnology Industry Organization (Washington, DC, USA), says that although the USDA review focuses primarily on GM plants, it is very forward looking and could stimulate similar reviews of regulatory issues for a broad range of biotech products by other agencies such as the US Food and Drug Administration (Rockville, MD, USA) and Environmental Protection Agency (Washington, DC, USA). "From a global consideration, the United States, as the leader in this technology, has the resources, ability and obligation to provide a road map to other rule-making bodies as they develop their own regulatory standards," he says.

Jeffrey L Fox, Washington

India produces homegrown GM cotton

Swarna Bharat Biotechnics Private (SBBPL; Hyderabad, India), a consortium of seven Indian seed companies, is set to break Monsanto's monopoly on genetically modified (GM) cotton in the country by receiving licenses to two genes (with a third license due in April) that transfer resistance against a variety of local pests. The consortium hopes the commercialization of GM crops that are developed by local public research laboratories will allow India to enter an era of self-sustaining agbiotech development.

India is now developing its own GM technology to protect cotton from pests.

"We are going to source beneficial genes from any publicly funded laboratory where they are available," says Satish Kumar, managing director of the SBBPL. The consortium is set to license a 'lectin' gene (*LecGNA 2*) that produces a protein lethal to sucking pests, such as aphids, from the publicly funded Center for Plant Molecular Biology (CPMB) at the Osmania University (Hyderabad, India) by April, this year. The CPMB has already engineered rice that resists sucking pests, and the SBBPL plans to develop GM cotton with similar traits.

Already, the consortium has licensed two indigenously developed genes derived from the bacterium *Bacillus thuringiensis* (*Bt*) that protect cotton against bollworm (*Helicoverpa armigera*) and tobacco caterpillar (*Spodoptera litura*) from the National Botanical Research Institute (NBRI; Lucknow, India) for Rs.7.5 ($0.16) million over a three-year period and a royalty of 3%, in October 2003 (see **Box 1**). By combining the insect resistant technologies, the consortium could help save at least Rs.10 ($0.2) billion now spent on pesticides. Indeed, 90% of damage in cotton is due to bollworm and sap sucking pests that can wipe out an entire harvest, if unprotected. Indian farmers currently spend Rs.16 ($0.35) billion on chemical pesticides.

With its novel cotton varieties, SBBPL members—which currently command a 30% share of the total Indian cotton seed market—could claim a share of the Rs.30 ($0.66) billion-a-year *Bt* cotton market in India, currently monopolized by the joint-venture company Monsanto-Mahyco Biotech (Mumbai, India). *Bt* cotton represented an estimated 60,000 acres in the 2002–2003 planting season and 200,000 acres in 2003–2004, compared to 22 million acres for conventional cotton.

Local development of GM crops is "the best thing that has happened to [India's] biotech industry," says Virender Lal Chopra, president of the National Academy of Agricultural sciences (New Delhi). "Firstly, the know-how is indigenous; secondly, it provides for smaller players' access to a costly technology that has been the monopoly of multinationals." Kumar explains that the main benefit for consortium members is low cost "because we share the technology access fee." He expects the price of SBBPL seeds to be two-thirds of that of Monsanto's.

Low cost aside, the advantages of sourcing indigenous technology are "economic and strategic," adds Kumar. "Although 70% of the royalties from sales of Monsanto's seeds goes to the US company, there is no outflow of royalties in our case," he says. Indeed, profit made by public laboratories from licensing fees could be reinvested to develop more agbiotech products that serve local needs. "Secondly, we can get help from our Indian partners on regulatory issues" to help get product approval, unlike before when "foreign collaborators expected us to handle these on our own, sometimes leading to losses," Kumar adds.

Activist groups critical of Monsanto are happy about the impending competition. "So far, 42% of our transgenic cotton research has been based on Monsanto's gene and this is absurd," said Suman Sahai, convener of Gene Campaign (New Delhi). "Finally, we seem to be getting our act together."

Monsanto, however, is not afraid of competition. "The consortium is just in the beginning of a long process," says Ranjana Smetacek, the company's spokesperson in India. "Evidently our technology is well established and our gene has been colicensed to nine more Indian companies whose products are under different stages of development." Rather than being worried, Smetacek says Monsanto welcomes any move that makes the use of *Bt* cotton "more widespread." Yet, Monsanto suffered a regulatory setback on its latest *Bt* cotton hybrid developed for northern Indian states such as Punjab when the hybrid failed to be approved in 2003 because it is susceptible to curl leaf virus (*Nat. Biotechnol.* **21**, 590–591, 2003).

Meanwhile, NBRI's deputy director, Rakesh Tuli, says that his institute's parent body, the Council of Scientific and Industrial Research

Box 1 Indian GM technology exploits patent gap

Monsanto's patent for the *Cry1Ac* gene, which confers protection to plants against the pest bollworm, is not protected in India. The NBRI's team has therefore been able to develop its own version of the *Cry1Ac* gene by altering its promoters to make the gene more efficient in expression and stability, according to NBRI's deputy director, Rakesh Tuli. SBBPL licensed both *Cry1Ac* and another 'killer' gene called *Cry1EC*—designed and synthesized at NBRI—which is used against the tobacco caterpillar, "a major alternative cotton pest, especially in southern India," says Tuli.

But Ebrahimali Siddiq, former deputy director general of the Indian Council of Agricultural Research (New Dehli), says there could be hurdles of a legal nature. Although the NBRI has "modified" the Monsanto gene, he says the resulting GM plants could at best be described as "derived" varieties, which are unable to be registered under India's plant variety protection act (*Nat. Biotechnol.* **19**, 895–896, 2001). Furthermore, the indigenous *Bt* cotton could face legal objections from Monsanto after January 2005 when India is expected to recognize product patents under the World Trade Organization (Geneva) rules. "We do not know what happens then; only time will tell," admits Tuli.

Nevertheless, the consortium is now seeking regulatory approval in India for both *Cry1Ac* and *Cry1EC* with a view toward introducing the new *Bt* cotton by 2006. Yet this period could be cut by a year if biosafety evaluations and field trials are allowed to proceed in parallel. "Our only hurdle is time," says a SBBPL official. "Otherwise, we are well equipped to take on Monsanto." *KSJ*

(New Delhi) is examining in great detail possibilities for exporting the technology and preparing the list of countries where it could be patented. In addition, says Ebrahimali Siddiq, former deputy director general of the Indian Council of Agricultural Research (New Dehli), the consortium may try to exploit those GM technologies on crops for which patents held by multinationals are now expiring.

With such wide perspectives, the consortium could soon gain momentum across the country. Prabhakar Rao, managing director of Nuziveedu Seeds (Hyderabad, India), the largest company in the consortium, said the membership will soon reach 19 because "many other companies are wanting to join us."

KS Jayaraman, Hyderabad, India

US budget emphasizes bioterrorism countermeasures

The $2.4 trillion budget proposal from US President George W. Bush's administration for fiscal year (FY) 2005 features little in specifics for biotechnology, apart from a continuing priority to support programs in bioterrorism countermeasures that began several budget cycles ago (*Nat. Biotechnol.* **20**, 209, 2002). Nonetheless, in calling efforts to combat bioterrorism a major federal R&D priority, the administration implicitly supports a great deal in the way of biotechnology-related activities.

Administration officials say their approach to managing such programs changed fundamentally when the Department of Homeland Security (DHS) was created (*Nat. Biotechnol.* **21**, 10, 2003). However, although some relevant programs in bioterrorism countermeasures were consolidated into DHS, important programs of this ilk continue within several other federal departments, including Health and Human Services (HHS), Defense, Energy (DOE) and Commerce (DoC).

In round terms, the FY 2005 budget request for programs dedicated to combating terrorism includes $1 billion in R&D for DHS and $4.1 billion for HHS, an increase of $154 million. HHS's share includes $1.7 billion for programs at the National Institutes of Health (NIH; Bethesda, MD, USA); many bioterrorism-related basic research programs at NIH are directed toward developing new diagnostics, therapeutics and vaccines for dealing with microbial agents.

In a change affecting federal activities related to bioterrorism countermeasures, the 2005 budget request seeks $400 million for the Strategic National Stockpile, which would be transferred from DHS back to HHS, so it will be "better aligned" with HHS medical expertise. The stockpile contains drugs, vaccines and other medical supplies and equipment that can be delivered quickly anyplace in the country. Meanwhile, the administration is requesting $2.5 billion —a $1.6 billion increase—for Project BioShield, which authorizes the government to buy vaccines and medications for biodefense (*Nat. Biotechnol.* 21, 216, 2003).

Elsewhere in HHS, the Centers for Disease Control and Prevention (CDC; Atlanta, GA, USA) in coordination with the Food and Drug Administration (FDA; Rockville, MD, USA) will be working with DHS and the Department of Agriculture (USDA; Washington, DC, USA) to improve responses to bioterrorism through early detection. The CDC budget includes $130 million in FY 2005 for its role in this initiative, the largest component of which is an investment of $100 million in its human health surveillance project, "BioSense," that uses automated techniques to analyze health data.

The overall budget request for FDA is about $1.5 billion, with an additional $350 million expected to come from user fees that are paid by biotech, pharmaceutical and device companies. The FY 2005 budget includes $499 million, a 5% increase, for reviewing human drugs programs, and $173 million, a 2% increase, for biologics.

The FY 2005 budget would provide $3.4 billion for the DOE's Office of Science, including continued support for genomics research. At the National Science Foundation (NSF, Arlington, VA, USA), one of the few places where biotechnology is mentioned explicitly in the federal budget request, the administration is calling for an overall $5.75 billion budget, a 5% increase over FY 2004. Within the Bioengineering and Environmental Systems Division, which supports research to facilitate deployment of technologies for use in the medical, biotechnology and environmental arenas, the request for $49.7 million is down slightly from FY 2004 levels. Meanwhile, the budget request of almost $100 million for the NSF Biocomplexity in the Environment program remains level, whereas the $305 million request for the Nanoscale Science and Engineering program, which supports research leading to individualized pharmaceuticals, new drug delivery systems and nanobiotechnology, represents a $50 million increase over the past year.

USDA research, education and extension programs are funded at approximately $2.4