

## USDA appeases organic lobby

The US Department of Agriculture (USDA; Washington, DC) recently confirmed that it will not include genetically modified organisms (GMOs) and similar modern biotechnology methods among proposals for nationwide standards for defining organic agricultural practices that are due to be reissued later this year. While industry representatives criticize the decision as being purely political, the USDA insists its decision does not reflect a negative judgment about biotechnology. Meanwhile, supporters of the proposal remain concerned about segregation of organic farming practices from biotechnology.

The USDA decision "is political, not based on any realistic assessment of risks, benefits, or science," says Val Giddings of the US Biotechnology Industry Organization (BIO; Washington, DC), referring to the USDA proposal, announced during the 19th Annual Ecological Farming Conference, held in late January at the Asilomar Conference Center (Pacific Grove, CA).

The US Congress mandated standards for organic agriculture as part of the Organic Foods Production Act, which was incorporated into the 1990 Farm Bill. When the USDA issued proposals early in 1998 (*Nat. Biotechnol.* 16, 128, 1998), Agriculture Secretary Dan Glickman left open the possibility that GMOs, food irradiation, and fertilizing crops with reclaimed urban sludge could be considered compatible with organic agricultural practices. However, the department was soon barraged with some 275,000 responses, through which "the public registered strong disapproval," says deputy USDA Secretary Richard Rominger (*Nat. Biotechnol.* 16, 497, 1998).

A draft of revised proposals is expected sometime later this year, perhaps by early summer, according to Keith Jones of the USDA National Organic Program. "We are intent on delivering a rule that is the genuine article. . .to restore trust in USDA," he says. "GMOs were the single most contentious issue," says Rominger. "Since biotechnology is not in sync with organic practices and does not meet consumers' expectations, it will not be included in our revised proposals."

But this decision regarding GMOs does not reflect a judgment about the safety or utility of biotechnology or other practices being omitted from the organic standards proposals, Rominger insists. Instead, the proposals are aimed at "giving consumers informed choices about how food is produced." Moreover, he notes, USDA has "not drawn official conclusions about biotechnology labeling for conventional agriculture products."

In general, USDA is doing a great deal to promote biotechnology as a key part of mainstream US agriculture efforts. However, Rominger points out, the USDA is trying to show "sensitivity to small farms" and also recognizes that "organic agriculture is an idea whose time has come," and is of some interest in its own economic right: organic farming sales are growing at a 20% annual rate, with US retail sales topping \$4 billion in 1997.

Contrary to the notion that "organic" also means "local," Rominger says that developing US standards that can be accepted abroad will help US farmers who are seeking to sell their products in this expanding international market. He notes that consumers in the European Union purchase about \$4.5 billion worth of organic products, and those in Japan about \$1.7 billion per year.

Meanwhile, although proponents of organic farming applaud the revised proposals anticipated from USDA, they continue to express concerns about the impact of biotechnology on agriculture. "It may become more difficult to keep GMOs out of organic agriculture," says Frederick Kirschenmann, who heads a family farm (Windsor, ND) and is a member of the private-sector National Organic Standards Board that works closely with USDA on such policy issues.

Spontaneous genetic outcrossing of engineered crop plants, such as canola, can affect varieties in neighboring fields that are being

grown as organic, according to Kirschenmann. In Canada, for example, several farmers who were not planting engineered canola are occasionally finding "volunteer" plants in their fields containing engineered traits, he points out. "Food safety is not the primary concern, but our system of agriculture is at odds with a system where genetic engineering is applied."

"Genetic erosion, concentration of the seed supply, and the right of farmers to save seed are three major concerns," says Michael Sligh of Rural Advancement Fund International (Chapel Hill, NC). He and other critics of genetic engineering are concerned that through mislabeling or contamination, or because of marketing growth in mainstream agriculture, organic farmers will find it increasingly difficult to obtain the unengineered seeds they want. "Organic farmers shouldn't take on this burden, and labeling should be required of those who want biotechnology," he says.

"[The USDA's decision] may be good for biotechnology in agriculture if it provides a refuge under organic for those who prefer not to deal with genetic engineering," says Giddings. Moreover, he adds, "as for it being a setback in terms of the marketplace, I'm highly skeptical of that. I see nothing ahead except continued rapid, if not exponential, growth for genetic engineering and other technologies in agriculture."

Jeffrey L. Fox

## Synergen lineage may finally pay off

Third time lucky or three strikes and out? That's the \$7.2 million venture capital question for the 35 former Amgen employees and six venture capital groups investing in Array BioPharma (Boulder, CO). Array is a start-up offering expertise in medicinal chemistry and high-throughput screening on a fee-for-service basis to pharmaceutical and biotechnology companies. With one deal announced last month, two more pending, and venture capitalists, analysts, and even competitors commending the company's experienced management team and business model, Array BioPharma is in a better position to succeed than either of its corporate ancestors, Synergen and Amgen-Boulder.

Array BioPharma was born last July, a weekend after Amgen gave up trying to find a partner for its Boulder-based R&D operation and pulled the plug on what had once been the biopharmaceutical company Synergen.

Amgen bought Synergen after its interleukin-1 antagonist, Antril, failed clinical trials in July 1994 and the company was forced to hold a fire sale of its facilities, intellectual property, and net operating losses. In fact, Array BioPharma is housed in Synergen's first building, although Amgen declined to invest in the new company and is merely acting as its landlord.

Array's three working cofounders, Kevin Koch, Anthony Piscopio, and David Snitman (all former employees of Amgen at Boulder; a fourth cofounder, K.C. Nicolauo, is chair of the chemistry department at the Scripps Research Institute, La Jolla, CA), believe they are on a better path to success than their corporate ancestor Synergen because the idea behind the company stems from the more than 160 years of combined big pharma company experience of the company's employees, who come mostly from Pfizer, Glaxo, and