

ANALYSIS

representatives drawn from the national regulatory bodies within the EU. If the Article 21 committee approves the products, they can be marketed throughout the EU. Without that approval, they cannot. At present, the EC is holding the three maize varieties in limbo. The 60-day member-state comment period ended, for the AgrEvo product, in August 1996. All three companies have been waiting for over a year for their products to go to the Article 21 committee.

The companies involved are getting somewhat exasperated with the European regulations. "Our maize was grown commercially for the first time this year [1997]," says Ken Baker of Monsanto Europe (Brussels), "with the expectation that a year would be sufficient to get European approval." It is the surprise element in the EC's treatment of the

corn dossiers that a source with AgrEvo objects to. "After more than two years they are sending them to new committees. If they had been built into the process originally, then OK. But this [the DGXXIV committee review] was never written into the legislation." Willy de Greef of the consultancy firm Applied Life Science Strategies (Zwijnaarde, Belgium), who has been following European regulations for well over a decade, admits to confusion over the current situation. "I'm getting lost in the process," he says. "I can't see what the policy here is. Maybe there has never been a policy."

The three maize strains under dispute represent 0.5%–0.7% of the 1997 maize, but they could nevertheless have a significant impact on US-EU trade. Grain imports to Europe from the United States occur through

tenders issued by the EC. Those tenders will probably be made in early 1998, with the product not expected to arrive in Europe for several months after that. However, as Monsanto's Baker explains, "A lack of approval [of the new varieties] means that US corn producers cannot quote for the tender.... And that is a trade barrier."

The involvement of the consumer policy division of the EC, DGXXIV, in the assessment of the maize varieties may seem surprising in view of the fact that the products are intended largely as animal feed. However, DGXXIV defines its remit of "consumer health" very broadly to include animal health and welfare, plant health, and environmental health. The political strength of DGXXIV increased markedly in 1997 following the widespread consumer concerns throughout Europe about bovine spongiform encephalopathy.

Not content with stretching its remit, the environmental arm of the EC, DGXI, now wants to change the 1990 directive on deliberate release. Apparently operating a policy of "regulation through press release," EC Environment Commissioner Ritt Bjerregaard announced a number of revisions to the directive at the end of November. These include limiting approvals to a seven-year period, insisting on extensive postmarketing monitoring of environmental impacts before approval renewal, and making public information on the approval and the assessment report of scientific committees.

John Hodgson

Either DNA or protein, dummy

How should one test whether a food contains genetically engineered ingredients or not? At the beginning of November, the Standing Committee on Foodstuffs—a committee comprising representatives of national food regulatory bodies within the EU—rejected EC proposals that tests should be based on the detection of DNA. It also rejected the alternative proposal—that tests should detect protein. So the EC had to come up with a new scheme. Its next proposal, which emerged on December 3 and went for consideration to the Standing Committee on Foodstuffs on December 17, was that tests should be DNA-based, and if DNA is not detectable, a second protein-based test could be performed.

The several weeks that this huge intellectual leap naturally took to formulate meant, strangely, that there was insufficient time for the necessary legislative formalities. While the Standing Committee could see the proposals in December, it will not be able to vote on them until its meeting this month. "The regulators are either devious or stupid," commented one observer. "And as a taxpayer, I'd prefer that they were devious." *J.H.*

Research ministry makes companies a soft option

German academics, encouraged by government funding structures, are creating biotechnology companies based on their research. That might be a good thing if it were not for the feeling that these companies are doing exactly the same work as the institutes they grew out of. The number of companies in Germany is growing—as the government wishes—but the amount of real corporate activity is changing very little.

"It's one way to cope with the shortcomings of public money [for academic research] and to overcome finance problems," says Iduna Fichtner, a researcher at the Max-Delbrück Centrum (Berlin). She founded Experimental Pharmacology and Oncology (EPO; Berlin) in January last year and still works at the Max-Delbrück Centrum (Berlin). Money that Fichtner received from the German Federal Research Ministry (BMBF; Bonn) to start EPO covered two thirds of the company's research and personnel costs. In her academic research, government grants—

also from the BMBF—covered only one third of those costs.

EPO has generated its own revenues. It provides services to the pharmaceutical industry in the molecular identification of cancers, and has won around 15 contracts since its inception. That money has allowed Fichtner to meet the expense of having 6 scientists working for the company. However, the boundary between the finances of EPO and those of Fichtner's academic research is fuzzy. "The [contract] money is [also] used to support my academic research, which would normally be funded by the government," said Fichtner.

There are now around 16 biotechnology companies affiliated with the Max-Delbrück Centrum in Berlin operating under similar circumstances. One is Transgenics, which offers services in transgenic mice and constructs knockouts. Jörg Pöttsch, its coowner, left MDC when he formed the company just over a year ago, but he remains in close contact with his old institution. Strikingly, the entire

advisory board of Transgenics comes from the MDC and is still there conducting the same kind of research as Transgenics. "There isn't a big difference in the technologies we use and those at the MDC," Pöttsch said. Transgenics received around DM 2.0 million (US \$1.12 million) in government funds to start the firm.

At present, German soft money for biotechnology startups is available through federal research programs, through state programs for business development and research, and through the German interregional biotechnology competition, BioRegio. To receive funds, companies do not have to do much more than convince the funding agencies that there is some commercial prospect for the technology, a task made easier by the federal research ministry's current enthusiasm for adding to its tally of home-grown biotechnology companies.

The picture is much the same elsewhere. Günter Kamp established Applied Molecular Physiology (AMP; Telgte, Germany) in