BIOTECHNOLOGY

CUTTING THE HEART OUT OF EUROPEAN BIOTECH?

Executives fear that EC rules amount to 'a moratorium in disguise'

An announcement last March by British regulators should have been good news for biotech companies the world over. For the first time anywhere, a food product that contains a genetically manipulated live organism was approved for sale. Holland-based Gist-Brocades had spliced two genes from one strain of baker's yeast into another, creating a combo that makes bread rise faster. Despite public fears in Europe and the U. S. about the safety of food laced with foreign genes, the yeast will carry no special label when it goes on the market later this year.

It may not be that easy from now on for companies, many of them U. S.-based, that want to sell genetically modified products in Europe. In its quest to create a single market by 1992, the European Commission in late April passed guidelines that will regulate the research and marketing of certain gene-spliced products. Each country has until October, 1991, to implement laws reflecting the guidelines. And a lot depends on how those are written. If they streamline the review process, manufacturers might in effect be able to get new-product approvals from all 12 European Community countries at once, rather than the current and costly one-by-one approach.

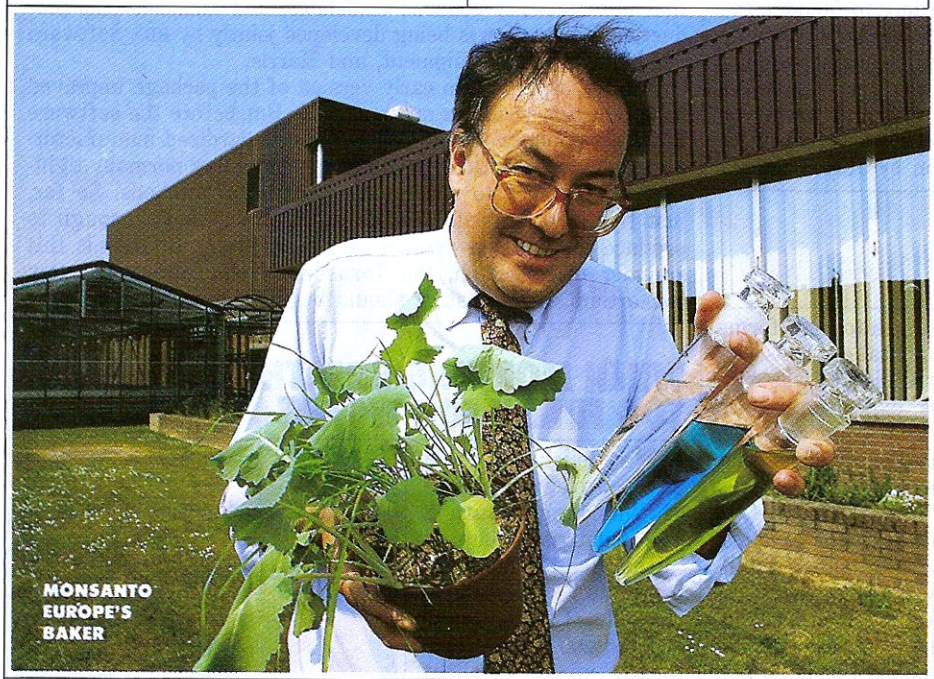
But many biotech executives fear the worst: On top of onerous permit requirements and special assessments of risk, any country could stall approval of a product for the entire continent by triggering possibly interminable reviews at the EC. That would set back European biotech companies, which are already considered at least three years behind the U. S. and Japan. It could also hurt U. S. companies that aim to sell in Europe. The new rules amount to a "moratorium in disguise," declares Kenneth M. Baker, director of biotechnology science and policy at Monsanto Europe. He and others worry that the guidelines, which have yet to be ironed out, also may require manufacturers to reveal competitive information.

'CONTAMINATE.' The rules also open up the possibility of submitting field trials and some lab research to sometimes emotional public comment. That could stall biotech commercialization in other countries the way it has been stalled in West Germany, where the environmentally active Green Party has used lengthy public hearings to delay approval of production facilities. In response, companies such as Bayer and BASF have sent production and some important R&D units to the U. S. Now, similar opposition "could contaminate the rest of Europe" and drive away local investment, says Guido Boeken, public affairs director at Belgium's Plant Genetic Systems.

Ironically, Germany has passed a law that virtually bans public hearings for proposed bioengineering facilities. But the Greens' strength is growing around Europe, including France and Britain, and they likely will press legislators who are writing the new biotech guidelines into law. Indeed, critics roasted British officials last spring for not inviting public debate before approving Gist-Brocades' yeast.

Of the two guidelines, the most controversial focuses on products containing live, genetically manipulated organisms (GMOs) intended for release into the environment. These include everything from Monsanto's disease-resistant strains of tomatoes to rabies vaccines currently being tested by France's Rhône Merieux. A handful of such products are already on the market. But trials on 200 more have been launched worldwide in the past few years.

The fear over GMOs is that modified bacteria and plants could interact in unanticipated ways in nature. A bacteria



MONSANTO EUROPE'S BAKER

JEAN-PIERRE THOMAS

WHAT THE NEW RULES REQUIRE

For genetically modified organisms to be included in commercial products:

- Research or field trials must be approved by a country's regulators and is subject to comment from other EC countries
- Marketing a product must be approved by one EC country, pending approval of the other 11 within six months. Any objections are to be resolved by an EC environmental committee

For biotech research or production using genetically modified organisms:

- National regulators must be notified to varying degrees, depending on the project and the hazard level of substances. Potentially competitive information may be required and approval can be subject to public hearings. The toughest requirements are on industrial production using infectious organisms

DATA: BW

with a new pesticide gene, for example, might affect a wide range of species—or even pass on the gene—thus throwing the ecological balance out of whack. So far, most concerns have not been borne out, and companies are having little trouble getting approval for field trials in the U. S.

But in Europe, the approval process could turn into a marathon. If any EC country objects to marketing a GMO product, the conflict will have to be settled by an environmental committee of the EC. That's in addition to product safety reviews conducted by other EC and national regulators.

This separate review doubles the chances that an application will be turned down, argues Jean E. Lunel, scientific adviser at French drug-and-chemical giant Rhône-Poulenc. It also makes the process more expensive for companies. According to Monsanto's Baker, just the cost of preparing the extra application could raise registration expenses for the typical bioengineered agrichemical product by 70%, to nearly $14 million.

NO STRAWBERRY ICE. There may be a blessing in all this, however, if the special scrutiny insulates manufacturers from the backlash of public fear. In 1986, public pressure caused postponement of a field trial in California of Advanced Genetic Sciences Inc.'s bacteria that prevent frost from forming on strawberry plants. Fearful of similar opposition, Monsanto still hasn't tested bacteria that have been given a gene to produce a natural pesticide.

In the U. S., companies now realize the inevitability of special biotech rules: "The bottom line is that the public has concerns, and industry now has to address them," says Pamela J. Bridgen, executive director of the Association of Biotechnology Companies. Last April, Wisconsin and Minnesota passed temporary bans on the use of a genetically engineered hormone that boosts milk production in cows. North Carolina recently required companies to submit data from GMO field trials to state as well as federal agencies. And an aide to Representative Robert A. Roe (D-N. J.) is readying a federal law like the EC's to fill in gaps in federal rules and preempt the growing patchwork of state laws.

The pressure will only intensify, especially as gene-altered organisms find their way into food. Being open with details of experiments "is a necessary prerequisite for public acceptance of a new technology," says Carlo Ripa di Meana, EC commissioner for the environment. Indeed, the biotech industry might be better off enduring the probing of regulators than that of a nervous public.

By Jonathan B. Levine in Paris, with John Carey in Washington

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