

EUROPEAN LEGISLATION

HOECHST DECISION SPURS ACTION

LONDON, U.K.—The government of the Federal Republic of Germany has gotten itself into a sticky situation after the decision of the state court of Hessen to prevent Hoechst AG (Frankfurt, F.R.G.) from producing human insulin (*Bio/Technology* 7:1213, Dec. '89) until a legal framework is in position to regulate genetically engineered products. But ironically, the action of the citizens' groups in stopping Hoechst may accelerate the industrialization of gene technology in Germany. Following some slick political maneuvering, it now appears that the government may be able to both cover its embarrassment and provide the country with a Gene Law within a few months.

The ban on the Hoechst facility effectively places a moratorium on the industrial use of genetically engineered organisms. According to Horst Segger, strategic marketing planning manager at Gruenthal (Stolberg, F.R.G.), although the ban does not explicitly extend to other companies, it would be a brave judge who, in the light of the decision, would rule in favor of the genetic engineering company. Segger said that Gruenthal, which hopes to be able to manufacture second-generation tissue plasminogen activator and second-generation prourokinase, had been optimistic that it would be able to obtain permission to proceed in the first quarter of 1990. Now the question is more whether the company will conduct the work in Germany, at all. At present, Segger said, "We believe we can go with Germany, but we are not as sure as we were one-and-a-half years ago." BASF (Mannheim, F.R.G.) has already made it plain that it would consider moving its production elsewhere, possibly to the U.S.

This sort of industrial pressure, combined with the fact that the relaxation of the Hessen court's ban is contingent on the enactment of a law, is the cause of the government's embarrassment. According to Wolf-Michael Catenhusen, chairman of the Bundestag Research and Technology Committee, the government had virtually full agreement on the need for a law among the Liberals, Christian Democrats, and Social Democrats in the Bundestag back in January 1987. Since then, however, bickering involving the Health Office and the Environmental Agency over the administration of procedures under the law has caused delays.

The Hessen court decision might ultimately be overturned, but that

process would take years—clearly too long for most German companies (except Hoechst, which has already invested heavily in its plant) to wait. Therefore the government is interpreting the decision as indicating that the Gene Law is needed as soon as possible. Consequently, it has rescheduled the bill's passage through parliaments. With the approval of the Social Democrats, a special subcommittee has been formed to tackle the bill, an unusual occurrence in Germany's parliamentary process. With this catalyst in place, the bill has already had its first reading in the Bundestag. Its second, and final, reading in the Bundesrat (the House of State Representatives) is due in April. The intention is to have the Act in force by June 1.

This timing could be crucial to the bill's passage. There are state elections in Northern Westphalia and Lower Saxony on May 13th; in Lower Saxony, at least, where the Christian Democrat/Liberal coalition is under threat from a "Red/Green alliance," the political complexion could change.

Whether this schedule will provide sufficient time for adequate discussion of fine details is still questionable. As it stands, the bill sets out rules for licensing procedures for products from genetically engineered organisms and proposes that the state, rather than federal, authorities should administer them. This could lead to multiple standards within the F.R.G. The bill also provides for substantial public access to the documentation of each application, and requires that arguments must be aired publicly in any licensing hearings. It is unclear whether the Hessen decision applies to research.

One experiment that has already caused considerable controversy is the proposed outdoor cultivation of transgenic petunias by Heinz Saedler's group at the Max-Planck Institute in Koln. Although he has heard that he has received the okay to go ahead, he has not received written confirmation.

Saedler believes that the petunia experiment serves two purposes—one scientific, the second political; "We still have to find out what you can do in principle in this country. We still have to break the problem we have in public acceptance of the whole of this technology. We have to bring to public notice the fact that we stick to the rules."

—John Hodgson

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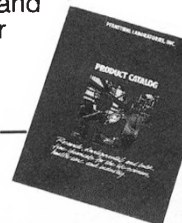
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