Tsukuba bucks tradition to boost academic-industry ties

Tokyo. Tsukuba University, based in Tsukuba Science City north of Tokyo, is flying in the face of Japanese university tradition by taking a bold initiative to promote links with government research laboratories and company research institutes in the science city.

Next month, the university will start recruiting scientists worldwide for a new research organization called the Tsukuba Advanced Research Alliance (TARA). TARA will have more than 200 faculty members, most of them on temporary contracts, and aims to cultivate interactions between government, industry and academic institutions.

The new body will focus on nanotechnology, biological sciences — such as gene regulation, cell-cell interactions and neural functions — multimedia and information management, research management and technology transfer.

It is the first such university-based organization in Japan. With nearly 50 government research institutes and more than 200 private-sector research institutes in Tsukuba, the opportunity seems "obvious", says Tsukuba University's president Leo Esaki, who won the Nobel prize for physics in 1973 and came to Tsukuba in 1992 from IBM.

Last year, the university established a

Esaki: opportunity was 'obvious'.

"study centre" to bring together researchers from public and private research organizations to hold regular symposia and seminars on selected research topics. Out of this emerged the TARA concept which has won substantial funding from the Ministry of Education, Science and Culture. In the budget for fiscal year 1994, which is expected to be passed by the Diet in June, ¥3.6 billion (US\$34 million) has been set aside for a central building, equipment and facilities.

Annual running costs are estimated at ¥4.8 billion yen. A substantial proportion of this will come from private sector sources and government agencies other than the education ministry — highly unusual for a Japanese university.

According to Esaki, many companies, including electronics companies, and pharmaceutical and chemical manufacturers are keen to join TARA to participate in contract and joint research. Esaki expects to raise about ¥110 million a year in research funds from such companies and other government organizations, such as the Ministry of International Trade and Industry and the Science and Technology Agency.

One unusual feature of TARA is that about half the researchers will be recruited from outside the university. TARA will also be able to offer permanent contracts to foreign scientists, following recent changes in university regulations.

Projects will be subject to regular external review by outside scientists, including non-Japanese, again a rare occurrence in the Japanese university and government research system.

David Swinbanks

Concern grows over reaction to deaths in clinical trials

Washington. The deaths of five out of 24 patients taking part in a National Institutes of Health (NIH) drug trial was preceded by a catalogue of errors on the part of the researchers and the sponsoring drug company, according to the Food and Drug Administration (FDA).

But the FDA, having sent warning letters to researchers and companies involved in last year's trial of the drug fialuridine for the treatment of hepatitis B, plans no direct sanctions, provided changes are made to avoid repetition of the errors.

Angry public health groups and congressmen, led by Edolphus Towns (Democrat, New York), chair of the House of Representatives government operations subcommittee, are complaining that agencies are closing ranks to defend the conduct of the trial. In a statement, Towns described the FDA action as "nothing more than a slap on the wrist", and promised summer hearings on the case.

An interim investigation at NIH last summer found that the trial had conformed to NIH procedures. But a more thorough investigation by an outside panel — chaired by David Challoner, vice-president of health affairs at the University of Florida — will deliver a more critical report to Harold Varmus, director of NIH, this week. Donna Shalala, the Secretary of Health, has asked the Institute of Medicine to follow that through with its own independent study.

When the patients died, the initial response of the agencies suggested there had been a tragic but unavoidable accident (see *Nature* 364, 275; 1993). But the FDA letters paint a darker picture of researchers and drug makers turning a blind eye to previously known problems with fialuridine.

The letter to the principal investigator on the trial, Jay Hoofnagle of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), accuses him of failing to give trial participants relevant information about fialuridine in informed consent documents, and of failing to respond appropriately when side-effects arose.

In addition, the drug's manufacturer, Eli Lilly of Indianapolis, is accused of failing to oversee the trial adequately. Revised trial guidelines prepared and implemented by the FDA since the deaths give the manufacturer more explicit responsibility for overseeing trials and, in particular, for ensuring a better flow of information about side-effects from separate trials of the same drug.

Both Hoofnagle and Eli Lilly must respond to these accusations by the end of the month. Sanctions are threatened unless they act to prevent something similar happening again.

Colin Macilwain

Gene-altered tomatoes face new protests

San Francisco. Consumer groups have responded rapidly to last week's official approval of the first genetically engineered whole food, the 'Flavr-Savr' tomato, by preparing a boycott and public 'tomato squashes' to demand labelling of biotech foods.

"We're going to ask every supermarket chain not to stock this tomato," said Jeremy Rifkin, the anti-biotechnology activist. "Otherwise they'll have to label every tomato." The Union of Concerned Scientists has issued a statement describing the government's oversight efforts as "inadequate and potentially dangerous".

On 18 May, Calgene Inc. of Davis, California, won permission from the Food and Drug Administration (FDA) to begin selling the gene-altered tomato which can be left to ripen on the vine, and lasts longer in shipping and on grocery store

shelves. The FDA did not ask Calgene to label its product, and has said it will not require any special labelling of genetically engineered foods.

Calgene volunteered for regulatory scrutiny to ease consumer concern about safety. It has also said it planned to mark each tomato with a "genetically engineered" label. But last week, the company said it would test a variety of labels, including some that did not mention the biotechnology process.

The company says that the tomatoes will be on sale in Midwestern states and California by early June. But several California grocery stores said they would wait and see how customers responded. They also said they were not selling milk from cows treated with bovine growth hormone, another controversial genetically engineered product. Sally Lehrman