ning commercialization of products derived from the four most widespread GM corn varieties (*Nat. Biotechnol.* **18**, 1137, 2000).

Moreover, on July 23, 2001, a metastudy by the French food safety agency found that 7–41% of conventional lots of corn in 2001 contained GM seeds, even though the levels in individual samples were significantly lower than in 2000 thanks to the self-control system. (France is the biggest seed producer in the EU, exporting mainly to Germany, Italy, Belgium, and Holland.) "Based on the French data, we can expect adventitious presence of such GM corns in many lots sowed in Italy," says Norberto Pogna, director of genetics at the Experimental Institute for Cereal Research in Rome, "but if we should take literally the zero tolerance claim and the August 2000 decree, we would end up preventing the Italian food industry from using the national harvest."

The Standing Committee is expected to prepare a revised text on which to vote. But negotiations could take several months, blocking the EC's plan to have the new rules enforced by the end of the year.

Anna Meldolesi, Rome

Japanese rules hinder commercialization of publicly funded projects

Japan's Kazusa DNA Research Institute announced a deal in February to supply the Canadian company MDS Proteomics (Toronto) with nearly 2,000 high-quality full-length human cDNA clones for protein interaction studies—a shift for the institute from sequencing toward functional genomics. Kazusa's director believes the deal with MDS came about because the nonprofit institute has consistently declined government agency genomics funding, which, despite rising dramatically in recent years, comes with outdated technology transfer conditions attached that impede subsequent commercialization.

Public sector genomics funding in Japan has increased dramatically from a few million US dollars a few years ago to more than US$600 million in 2001, as part of a government effort to redirect research funding towards areas with high economic potential. For this investment to be realized, say observers, results must be commercialized, with public institutes and universities engaging more actively in technology transfer and partnering with industry.

However, opportunities for technology transfer in Japan itself are limited. For example, domestic biotechnology comprises either large firms and "old" manufacturing and process-oriented biotechnology dating from the 1980s, or small, inexperienced companies created recently.

Moreover, collaborations with both domestic and foreign firms are thwarted by public funding conditions. "Government funding in Japan comes with a lot of strings attached," says Michio Oishi, Kazusa's director. "Rules for project management are highly inflexible and existing intellectual property [IP] rights regulations often make it difficult to cooperate with industry. In a highly dynamic research field like genomics, either is inappropriate."

Regulations and established practices concerning patent rights are a particular problem. "Under present regulations for research investment grants, patents are owned by the Japanese state and are to be licensed to all companies on equal terms," explains Yusuke Nakamura, director of the Genome Center at the University of Tokyo's Institute of Medical Sciences and head of the RIKEN SNPs Research Center. "Such a policy is the exact opposite of what patents are supposed to be all about. There isn't much point for universities to obtain patents as long as this way of thinking continues."

Companies are also deterred from striking deals with public-sector organizations because of the difficulty in obtaining exclusive agreements without triggering an outcry from other firms. For instance, last November Third Wave (Madison, WI) managed to acquire from the RIKEN SNPs Research Center the exclusive rights to all research and clinical applications emerging from a database of nearly 3,300 SNPs located on some 200 genes related to drug metabolism. The genetic markers were discovered as part of a large genotyping effort financed by the Japanese government's Millennium project, and the deal triggered loud protest from Japan's pharmaceutical industry and the industry-financed Pharma SNP Consortium (PSC) protesting the sale of the fruits of research funded by domestic taxpayers' money to foreign corporate interests. (RIKEN claims it had initially offered the deal to selected PSC companies but was turned down.)

In the US, the Bayh–Dole Act encourages the exclusive licensing of IP held by publicly financed nonprofits (such as universities) to private firms. Although efforts have been made to introduce important elements of the Bayh–Dole act in Japan, implementation has been blocked by conservative ministries, most notably by the education ministry, the largest funder of research in Japan. And after the fracas over the RIKEN/Third Wave deal, some are now arguing that exclusive licensing agreements should be formally restricted to domestic companies only.

To get around current restrictions, the Kazusa Institute has so far resisted accepting funding from government agencies, according to Oishi. Instead, Kazusa has confined itself almost entirely to funding from the local Chiba prefecture government (located east of Tokyo)—a highly unusual situation in Japan. Around 90% of the institute's ¥1.9 billion annual budget (US$14.3 million) comes from Chiba, which doesn't attach IP or agreement conditions to its funding. (The other tenth comes through licensing agreements.) "I don't say that it would have been impossible to enter an agreement with a biotechnology company like MDS Proteomics had we accepted government funding in the past. But it's certain that we would have gone through a whole lot of trouble," says Oishi.

Kazusa was the first large-scale sequencing center to be set up in Japan, after an unsuccessful effort at the RIKEN Tsukuba Center to develop an automated high-throughput sequencing system. Despite limited funding and increasingly outdated equipment, it is still one of the leading genomics research centers in Japan. However, faced with a rapidly deteriorating financial situation on the part of its main sponsor and the urgent need to diversify its activities away from sequencing toward functional genomics, the institute may soon be forced to seek an infusion of government funding. "I certainly hope that government regulations change before the day we need to go to Kasumigaseki [where national government agencies are located] to ask for money, but I don't think it is very realistic to assume that this is indeed going to happen," says Oishi.

Meanwhile Nakamura warns there will be little commercialization of public sector research in Japan unless it is recognized that patents are of no value if they are not used. "Without due considerations on commercialization issues, and without evaluation standards that put an emphasis on the use value of intellectual property, the waste of research money in this country won't stop."

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