limit to the number of such genes," he says.

Because the rights of almost half the biotechnology-related patents registered in Japan are held by US companies and institutions, the government is keen to encourage biotechnology-related patent filings (especially those based on genomic information), which it sees as key to strengthening the nation's biotechnology industry.

The first stage of the new program will focus on the creation of vast databases of genomic information, with a view to providing the data to Japanese research institutions and biotechnology companies for the development of new products and technologies in such areas as chemical engineering, pharmacogenomics, and agriculture.

In the past, genome research in Japan has been rather disorderly, with ministries carrying out individual genome projects. Now, five science-related ministries and agencies, including the Science and Technology Agency (STA; Tokyo) and MITI, will collectively promote the commercial application of research into human, animal, and plant genomes.

Initially, the focus will be on the functional analysis of DNA, with the Genome Sciences Centre (GSC; Wako City), a new institute set up last year by the Institute of Physical and Chemical Research (RIKEN; Wako City), taking the central role in human and animal research for the genome databases.

It is hoped that the high-speed DNA sequencer developed by RIKEN will lead to a speedy completion of GSC's "gene encyclopedia" of partial sequence data of more than 20,000 full-length mouse cDNA clones, which accounts for 20% of the entire genome. "It's never too late to put an extra effort into genome research," says Oishi.

Analysts predict that the emergence of new analytical technologies, including DNA sequencers and biosensors, will lead to a huge expansion in information-processing technologies. They say that the new government program will not only help create new biotechnology businesses, but will also allow companies formerly unrelated to biotechnology, for example in electronics and multimedia, to "join the force."

The new program will be partly financed by this year's supplementary budget, with the main part of its funding coming from the annual budget taking effect April 1, 2000. Although the budget for the current fiscal year already features ¥284 billion (US$2.4 billion) funding for biotechnology-related projects, such as those included in the "social infrastructure program" aimed at stimulating the economy (*Nat. Biotechnol.* **17**, 126–127, 1999), such projects are likely to attract even more funding following the launch of the new program.

Specific policies, such as those related to industry reform and intellectual property protections, will be discussed in April following the creation of a new interministerial committee for the program.

Asako Saegusa

European Parliament considers release of GMOs

The European Parliament (Strasbourg) has adopted a mixed bag of new amendments to directive 90/220/EEC, which is the framework for the safe environmental release and marketing of genetically modified organisms (GMOs). The amendments stand both to nurture and further constrain the GMO product market in Europe.

Although there were more than 20 new amendments and many additions made, "The big one [amendment 5] is the time limit on approvals," states Willy de Greef, head of regulatory affairs at Novartis Seeds (Basel). He explains that regulators approve a particular event (meaning a crop produced from a GMO), as opposed to a particular plant variety. "Then, we begin breeding programs to create different varieties adapted to different environments," he says. "If the approval is for 10 years, and 5 [of those] are dedicated to creating varieties, this is a severe constraint." After 7 years, a company will become hesitant to invest in further development," he says.

Other directive amendments define the need to identify the genetic alteration, routine registration and logging procedures, and such precautionary measures as a ban on GMOs that contain genes expressing antibiotic resistance (amendment 90), or that pose an "unacceptable risk" to biodiversity (amendment 91).

"One thing we applaud is the reference to setting up a centralized procedure 'assessment' agency [amendment 96]," says de Greef. Amendment 96 states that the long-term goal of the European Union (EU; Brussels) should be to create a centralized procedure at the European Community level along the same lines as those guidelines used for the licensing of medicinal products. The amendment goes as far as to suggest that the European Environment Agency in Copenhagen conduct a study on the possibility of centralized monitoring of the release of GMOs.

"What makes Europe attractive is the existence of the common market and a common standard that applies across the member states. Having one door to enter into the process will be a very significant improvement," says de Greef. Tom McDermott, spokesperson for Monsanto (Brussels) concurs: "We welcome any changes that would make the system work better." Under the current system, companies can go through the lengthy process of applying from country to country or choosing a rapporteur country to present their application to the EU member states.

Monsanto, Novartis, and other companies seeking approval of GMOs for the European market have grown to expect the unexpected while wading through EU bureaucracy. And the climate surrounding biotechnology, especially agricultural biotechnology, has been erratic. Public suspicion and nongovernment organizations lobbying against GMOs have prompted some legislators to tiptoe around the issue. For example, during the EU scientific committee's February vote on Monsanto's two varieties of genetically modified cotton, several nations abstained, making it impossible for Monsanto to obtain the necessary weighted majority of favorable votes to gain approval. Monsanto must now wait until June at the earliest before its cotton proposal is put in front of the EU council of ministers for a decision.

"The [approval] process is very unpredictable, takes a long time, and can be very cumbersome," comments McDermott, "and there is a political element and other considerations that contrast with how the regulatory process is handled in other parts of the world". de Greef also acknowledges that the EU needs to build more transparency into how regulations are set up and that the continent needs regulatory institutions that are as highly regarded as the US FDA or USDA.

Despite the complexities, the mood at both Novartis and Monsanto is optimistic. "Clearly there are fractions in the [EU] parliament that are anti-biotech, namely the Greens, but nobody else is really opposed," says de Greef. "What is needed is a good understanding of where biotech would fit in for sustainable agriculture, and we have a long way to go in communicating it. We must improve the dialogue with society, and that will take about 5–10 years. We are in for the long term."

The amended directive now moves to the European Council of ministers for a vote. Their redraft is then reconsidered by parliament before incorporation into the national law of EU countries.

Barbara Nasto

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