pointing out that it "holds the promise of dramatic and useful advances." But the report also draws attention to the need to achieve "sustainable agriculture" in developed and developing countries amid the "fragility of natural systems," noting that "800 million people are undernourished and 200 million children under five years of age are underweight." In this context, it speaks of both "biotechnology and other technologies" contributing to those laudable efforts—subtly downplaying the potential of biotechnology to serve the needs of the developing world.

Notwithstanding the many differences between the EU and US approaches to regulating agricultural and food biotechnology products, the report calls for making all those processes "sufficiently strong to ensure public confidence" and cautiously points out this "may necessitate strengthening [those] regulatory systems…in some respects." But abandoning such cautions, the forum report shortly recommends several major steps toward strengthening those regulations in ways that, if implemented, would substantially change the way US officials handle biotechnology crops and foods derived from them. In addition to recommending mandatory food labeling, the report also calls on governments to develop and implement procedures for tracing all foods derived from GM organisms and for monitoring environmental effects. Not only does the report call for "mandatory premarket examination" for GM foods and animal feeds, but it also recommends that they be "approved for sale only after they are found to meet the standard of presenting a reasonable certainty of no harm."

That recommended standard appears to exceed current US regulatory practices. The report also urges going beyond current doctrine that biotech foods are "substantially equivalent" to conventionally produced food. Thus, it says, deeming a biotech food substantially equivalent "should not be taken automatically to mean that it needs less testing or regulatory oversight." The report also seems to favor applying a modified form of the vaunted precautionary principle to this field, albeit couching that endorsement in cautious terms: "When substantive uncertainties prevent accurate risk assessment, governments should act protectively on the side of safety."

The State Department also carefully sidesteps endorsing substantive regulatory recommendations in the forum report.

Although most of the forum members are described as being very comfortable with its many recommendations for strengthening a variety of biotech agricultural and food regulations, deliberations within the forum over "content-based mandatory labeling requirements for finished products containing novel genetic material" proved difficult and led to a somewhat vague final wording of this provision, according to insiders.

But others interpret that wording very differently, saying it supports current US policies. The recommendation "does not suggest that labels be affixed to foods solely on the process by which they were created," says Michael Phillips, executive director for food and agriculture of the Biotechnology Industry Organization (BIO; Washington, DC). We are heartened to see support for content-based labeling regulations, rather than process-based. These reflect the current regulations enforced by the FDA." He also says that the report could prove "instrumental in ending the European moratorium on approval of crops and foods enhanced through biotechnology." Phillips explains this interpretation by noting that "many of the recommendations are consistent with existing US regulatory policies or those currently under consideration such as greater openness and the concept of substantial equivalency."

Meanwhile, advocates of toughening US biotechnology regulatory regimes likely will welcome the report, says forum member Rebecca Goldburg of Environmental Defense (New York), who interprets the report very differently from BIO's Phillips. "The report will be useful to people who want to push the envelope on regulatory issues, especially because of the diversity of the group who wrote it." She notes that many of the recommendations in the report that appear to tow the "US NGO [non-government organization] line are mainstream for Europe."

Jeffrey L. Fox

Japan's bioinformatics efforts misguided

Efforts by the Japan Biological Informatics Consortium (JBIC) to develop clinical bioinformatics are premature, according to analysts in Tokyo. The country's insistence on playing scientific catch-up coupled with the political heritage of such consortia means that JBIC is little more than a distributor of funds to large companies. Even independent efforts in this area could be thwarted in a country that is ill equipped for clinical genetic research.

JBIC was created as part of an effort by the Ministry for Economics, Trade, and Industry (METI; Tokyo) to revitalize the domestic biotechnology industry and help Japanese corporations enter the genomics era. JBIC was set up in November 1998 under the umbrella of the Japan Biotechnology Association (JBA), supported by several large companies, including Mitsubishi Chemical, Hitachi, and Fujitsu, and incorporated as a non-profit organization last July. The consortium is focused on bioinformatics tools for research and diagnostics, but its mission also encompasses the development of electronic commerce tools for the biotechnology industry. "This is going to be an exciting year for bioinformatics in Japan", insists Yukio Matsuura, general manager in the planning division of JBIC. He says the intermingling of software vendors, device manufacturers, and biotechnology companies in a single consortium is likely to boost the Japanese bioinformatics industry.

However, JBIC's prospects are at best uncertain. Toru Yao, a consultant on bioinformatics to the RIKEN Genomic Sciences Center (Yokohama) agrees that "JBIC is a big step forward in bioinformatics in Japan." But he points out that, in the traditional fashion of R&D consortia in Japan, the rationale of JBIC has been more with a broad diffusion of information and knowhow rather than the fostering of innovative research. And although JBIC currently comprises some 75 corporate members, the consortium has failed to attract any of the handful of dedicated bioinformatics startups in Japan.

While JBIC officials put this down to the high annual membership fees of US$10,000, Matsuura concedes that JBIC lacks an infrastructure and strategy to support and encourage bioinformatics startups. As a result, most of the US$130 million that JBIC has spent in research grants over the past two years has been awarded to large corporations, particularly those involved in IT. While there is some optimism that Japanese pharmaceutical companies will considerably increase general bioinformatics spending this year, Matsuura admits that the consortium is being pushed increasingly toward

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clinical bioinformatics as it caters to the interests of its large IT company members. "If it isn't clinical bioinformatics, it is difficult to convince large electronics companies to invest in bioinformatics," says Matsuura. "R&D is a niche market with limited prospect for exports. That just isn't interesting [to them]."

However, there is increasing concern about JBIC's focus on clinical bioinformatics, which some analysts say is surprising in a country that has very little experience in the clinical application of genetics. JBIC plans to evaluate the clinical usefulness of single nucleotide polymorphisms (SNPs) and is currently compiling a database of the allelic variation of disease-related SNPs, as part of a concerted government effort supervised by Yusuke Nakamura at the Institute of Medical Science at the University of Tokyo. But Jiro Nudeshima, a bioethics specialist at the Mitsubishi Kasei Institute of Life Sciences, points out that Japan's healthcare system is ill-equipped for clinical bioinformatics: There are virtually no guidelines for genetic testing in Japan, counseling services for patients are rare, and procedures for informed consent often inadequate. Furthermore, overall patient enrollment in clinical trials has dropped drastically over the past few years, prompting many pharmaceutical companies to relocate their clinical research activities to the US or Europe. While at least one Japanese pharmaceutical company (Yamanouchi) has announced clinical trials with "personalized" drugs in Europe, no such trials are being undertaken in Japan.

Moreover, ministerial politics and the consortium's strong affiliation with METI could present further difficulties for the JBIC. Affiliation with a ministry is required for all Japanese non-profit companies, and although JBIC is formally affiliated with the four ministries involved in biomedical research and biotechnology (METI; Ministry of Health, Labour, and Welfare; Ministry of Education, Culture, Sports, Science, and Technology; and Ministry of Agriculture, Forestry, and Fisheries), METI is the only ministry actually providing funds to JBIC. An endorsement by the health ministry is critical to JBIC's plans for clinical bioinformatics, but some analysts say that, due to bureaucratic rivalry with METI, the health ministry has little motivation to fully support JBIC. In the past, initiatives in healthcare informatics promoted by either METI or the former Ministry of Post and Telecommunications were often blocked in this way by the health ministry, according to Masayo Fujitmoto, analyst at the Sumitomo Marine Risk Research Institute who has studied the development of healthcare information systems in Japan.

Meanwhile, success in bioinformatics and its clinical application may rest with independent instrumentation and software companies, several of which have announced plans to upgrade bioinformatics activities this year. Hitachi Software Engineering (Yokohama), for instance, is currently constructing a new research facility focused on DNA chips and bioinformatics, while the software company Intec (Toyama), has released plans to float its bioinformatics subsidiary Intec Web & Genome on the Tokyo stock exchange.

Robert Triendl

Immunex takes premature step to guarantee Enbrel market share

In November 2000, Immunex (Seattle, WA) initiated a patient enrollment program designed to increase year-end sales of its anti-inflammatory drug Enbrel. Immunex claims the program was implemented because of fears that demand for the drug would outstrip supply. However, drug production has not reached capacity and Enbrel's market share does not appear to be in immediate jeopardy, suggesting that recruitment of patients onto Enbrel alone may simply have been a strategy to guarantee market share for the drug and boost fourth quarter sales.

In order to guarantee future access to Enbrel, a tumor necrosis factor (TNF) inhibitor, patients were required by Immunex to purchase the drug by the end of 2000, register with the company and, except under specific circumstances, use the drug exclusively or lose their place in the program. As well as ensuring sales to those currently taking the drug, this move encouraged potential patients, whose condition may not yet warrant treatment with Enbrel, to purchase the drug and enroll so as not to miss out on using the drug in the future. Indeed, some analysts expect the 70,000-strong rush to register for the program to result in an estimated $192 million in fourth quarter sales, sharply up from $152 million in the third quarter. Limiting patients to the exclusive use of Enbrel would also guarantee

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