

BUSINESS AND REGULATORY NEWS

New plan from industry to preserve Bt crops

This January, the members of an industry coalition consisting of companies that produce *Bacillus thuringiensis* (Bt) engineered corn seed outlined an industry version of a unified plan to preserve Bt insecticidal toxins and extend the useful lifetime of crop plants that are engineered to produce these insecticides. Monsanto (St. Louis, MO), Novartis Seeds (Greensboro, NC), Pioneer Hi-Bred (Des Moines, IA), and Mycogen-Dow Agro-Science (Midland, MI) are following the advice, given in June last year, of the members of a scientific panel convened by the US Environmental Protection Agency (EPA; Washington, DC) who urged the agency to “require the use of structured refuges” to preserve Bt-produc-



ing crops (*Nat. Biotechnol.* 15:499, 1997). So far, EPA is not insisting on a refuge set-aside, and the industry would prefer to implement a Bt-preservation program on a voluntary basis. Although details are being negotiated, the proposed plan calls for farmers who plant Bt-producing corn seed to set aside 20% of their cropland as refuges in which to plant conventional corn, some of which may be treated with conventional insecticides during the growing season. Because the proposal entails uniform refuge set-asides, it could lead to better compliance by growers because what they need to do to meet this Bt-preservation strategy is straightforward, according to a spokesperson from Monsanto.

Another hiccup at British Biotech

At the end of 1998, British Biotech (Oxford, UK) terminated a phase III trial of marimastat, its matrix metalloproteinase inhibitor cancer drug, after realizing that the design of the trial would not generate data suitable for regulatory approval. According to a company spokesperson, the end point of the trial—an unusual composite measure involving a combination of CT scans, levels of cancer antigens, and patient “well-being” (as opposed to survival)—would not produce data that the European Medicines Evaluation Agency (EMA; London) and the US Food and Drug Administration (FDA; Rockville, MD) would accept for approval. However, the company points out this is only 1 of 11 trials; the remaining 10, which cite survival as an end-point, will continue as they are. “Three-quarters of a million pounds will be saved” as a result of halting the trial, says the company positively, although £250,000 had already been spent on recruitment for the trial. The inadequacies of the marimastat trial were spotted during an external assessment of the company’s technology following the firing of its head of clinical trials, Andrew Millar, and the resignation of CEO Keith McCullagh last year (*Nat. Biotechnol.* 16:609).

More merger of markets

Euro.NM announced at the end of 1998 its intention to merge with the Stockholm bourse and the Copenhagen Exchanges, ending rumors of a merger between Euro.NM and Easdaq (*Nat. Biotechnol.* 16:1301, 1998). However, according to Clive Pedder, director of marketing at Easdaq, the problems that faced the potential Easdaq–Euro.NM merger—namely a lack of clarity regarding how a combined exchange would operate—are also a concern for the proposed new merger. Pedder thinks the concept of a merger between exchanges is valid, but that such ties are worthless unless a single set of rules regulates all the exchanges and they are all linked electronically. Robert Thys, director of marketing at Euro.NM—itsself a group of four associated exchanges from Germany, France, The Netherlands, and Belgium—says only that “each exchange will operate within its own framework.” Until the hurdle of complete integration can be overcome, says Pedder, “investors will continue to see the [new merged] exchanges as separate local markets, rather than a single pan-European one.”



BIO/TECHNOLOGY

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• **Do we need a special patent law for biological inventions?** In 1980, the US Supreme Court held that a living organism could be patented as a “manufacture” or “composition of matter” if it satisfied the other requirements of the patent laws. While this decision was a milestone for the biotechnology industry, it should not encourage a blind acceptance of the patent laws as they stand today. The development of a patent law, written with biological invention in mind, may serve to avert legal bloodshed in the future.

A rather pressing question at this time is whether the determination and isolation of the naturally occurring DNA molecule that codes for a natural product warrants the issuance of a patent on that molecule per se. While, speaking abstractly, a product of nature is not patentable, there are patents on purified products of nature such as epinephrine and vitamin B-12.

• **Dental gene cloned; may lead to better fillings and teeth.** Researchers at the University of Southern California School of Dentistry here have cloned the first dental gene, important in tooth enamel formation. They envision a day when the protein components of human enamel can be made into a pastelike mixture to replace the silver, gold, and artificial materials that dentists now use to fill cavities, and they hope their work may lead to genetic improvements in the human dentition.

• **Tech brokers focus on Japan biotech transfer.** The techniques of biotechnology have become sufficiently valuable world commodities that a few companies now focus on selling them, particularly to Japan and the Far East. While US computer and semiconductor industries have found that reaping the short-term financial benefits of transferring technology to Japan has damaged their long-term interests, there is little concern about this scenario in the US biotechnology community.

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