rations concerning Incyte's (Palo Alto, CA) LifeSeq DNA sequence and gene expression database: PathoGenome is available through nonexclusive subscriptions to companies for drug discovery.

What is different is that Genome Therapeutics will also offer some functional genomic modules that will allow exclusive collaborations in more narrowly defined areas. Genome Therapeutics already has two collaborative agreements—with Astra (Sodertälje, Sweden) for vaccine, pharmaceutical and diagnostic products effective against *Helicobacter pylori*, and with Schering-Plough (Madison, NJ) for *Staphylococcus aureus*. PathoGenome will provide the company with short-term cash while it fur-

ther develops its human functional genomics and pharmacogenetics capabilities, says president, chairman, and CEO Robert Hennessey.

In April, Merck (Whitehouse Station, NJ) announced its new in-house genomics initiative, the Merck Genome Research Institute, to develop methodologies to speed the association of function with sequences. A week later, it signed a research agreement with Lexicon Genetics (The Woodlands, TX) for large-scale analysis of gene function. In early May, the genetics specialist Sequana (La Jolla, CA) inked two deals. The first is to supply ZymoGenetics (Seattle, WA) with bioinformatics tools and sequencing technologies for paracrine/-

endocrine signaling molecules, and the second is an expansion of its asthma alliance with Boehringer Ingelheim (Ingelheim, Germany).

And Pharmacia & Upjohn (Kalamazoo, MI) is to expand its genome database collaboration with Incyte. The revised 4-year deal provides Pharmacia & Upjohn with access to the LifeSeq FL database of full-length genes, the LifeSeq Atlas gene mapping database, and the GeneAlbum reagent set. Pharmacia & Upjohn will also become Incyte's first partner for ZooSeq, a database scheduled for launch in June providing genomic data on model animals (rat and mouse to begin with).

Vicki Brower

EPA issues, USDA amends respective biotech rules

In April, following 11 years of delays, the US Environmental Protection Agency (EPA, Washington, DC) published final rules for reviewing "new" microorganisms developed for commercial purposes. Industry was unimpressed. But when the US Department of Agriculture (USDA; Washington, DC) Animal and Plant Health Inspection Service (APHIS) issued more industry friendly, simplified rules for introducing genetically engineered plants into open environments, environmental groups were perturbed.

A multitude of political and scientific hurdles blocked officials during the seemingly endless development and launch of the EPA rules. Some of these hurdles were ideological, such as the deregulatory fervor of Washington politics during the 1980s. Others were self-imposed. For example, in March, when news of Dolly the cloned sheep broke, EPA officials deliberately delayed publishing the Toxic Substances Control Act (TSCA) rules, lest members of the media and public think that the regulations covered mammalian cloning.

The EPA rules apply to the commercial use of "new" microorganisms formed by combining genetic material from organisms in different genera. Commercial uses of these microbes, ranging from the production of industrial enzymes and specialty chemicals to use as biofertilizers or in bioremediation, were previously subject to EPA oversight under the federal TSCA regulations. These earlier rules were invoked on the use of recombinant DNA. Now, the EPA claims, the "intergeneric" definitions reflect the agency's interest in environmental risk of microbes rather than the process through which they are formed (although it is hard to envisage how intergeneric microbes could be formed without recom-

binant DNA).

The delays in the launch of the regulations and the reduction of EPA oversight have tempered industry's reaction to the final rules. "A few years ago, the biotech industry was concerned that hundreds of new products would be affected by the TSCA rules," says Alan Goldhammer of the

Although industry seems unperturbed by the TSCA rules, there is some discontent—expressed informally thus far—among some sectors of the academic community in fields such as bioremediation and microbial ecology.

Biotechnology Industry Organization (Washington, DC), "But the fact is [that] relatively few of those products have come along, meaning the TSCA rules will affect a small segment of the industry."

The rules further deregulate intergeneric microorganisms used in contained fermentation applications. "From that perspective, the new EPA rules are of some importance," says Goldhammer. Also exempt are projects in which investigators comply with the US National Institutes of Health (Rockville, MD) "Guidelines for Research Involving Recombinant DNA Molecules," and outdoor testing on 10 acres or less for projects involving 2 particular nitrogen-fixing microorganisms, *Bradyrhizobium japon-*

icum and *Rhizobium meliloti*.

Although industry seems unperturbed by the TSCA rules, there is some discontent—expressed informally thus far—among some sectors of the academic community in fields such as bioremediation and microbial ecology. The feeling, which may congeal into formal representation in the next few weeks, is that the rules are not scientifically based and that they be burdensome to academic researchers (see "The EPA's war on bioremediation," pXXX).

Representatives of environmental organizations welcomed the TSCA rules, but they are not so happy about the amended APHIS rules that were issued by the USDA late in April. "USDA's promotion of biotechnology ahead of environmental protection is reprehensible," says Rebecca Goldberg of the Environmental Defense Fund (New York) about the new rules. "By applying notification procedures to essentially all transgenic crops, the rules refuse to take seriously the riskier types of transgenics."

The amended regulations simplify procedures for virtually all genetically engineered plants, expedite reviews, and adjust reporting requirements for field tests to make them more consistent, according to John Payne, director of biotechnology and scientific services for APHIS. For instance, although annual renewal notices still need to be filed with APHIS, investigators need not furnish the agency with results of field trials on long-lived plant species such as trees until those trials are completed, he notes. More importantly, the new rules make it easier to classify plant varieties as "nonregulated" when new products raise no risk, as crops in five species—maize, potato, cotton, tomato, and soy—have been classified in the past.

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