EPA finally issues TSCA and FIFRA rules

WASHINGTON, D.C.—After years of drafting, revising, and behind-the-scenes negotiating, officials of the Environmental Protection Agency (EPA, Washington, DC) recently issued two sets of revised proposals for regulating biotechnology. EPA Administrator Carol Browner characterizes the proposals as balancing the economic needs of the biotechnology industry with the EPA's responsibility to protect public health and the environment.

One set of EPA proposals delineates the agency's approach to evaluating modified microorganisms under the Toxic Substances Control Act (TSCA), while the second set of proposals explains how the agency will oversee small-scale field tests of certain pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In both cases, EPA officials labored to adapt their rules to federal statutes that were designed to deal with chemical products.

In cases where TSCA is the signal statute, EPA officials plan to regulate many intergeneric microorganisms—microorganisms engineered to contain genetic material from organisms in different genera—as "new chemical substances." When a biotechnology company, or some other concern, plans to manufacture, import, or otherwise use such microorganisms for commercial purposes, a "microbial commercial activity notice" needs to be submitted to the EPA 90 days in advance, so the agency can determine whether the microorganism presents "an unreasonable risk to human health or the environment." Moreover, EPA officials reserve the right to review plans for field trials of intergeneric microorganisms.

Although the scope of these TSCA rules is potentially universal, EPA officials are proposing several broad exemptions. For example, 10 microbes commonly used for making specialty chemicals, particularly enzymes, are already considered eligible for, and probably will receive, exemption from strict oversight. Moreover, some well-studied microorganisms, such as nitrogen-fixing soil bacteria, may be exempt from notice requirements when tested in field trials involving plots of ten acres or less. And experiments in contained greenhouses and laboratories may also be exempt from EPA oversight.

EPA's new proposals under FIFRA pertain to the small-scale testing and planned commercial use of microbial pesticides and plants engineered to produce pesticides. Although earlier proposals called for notifying the EPA of all contemplated small-scale field testing of all such pesticides, the newer proposals somewhat narrow that scope, exempting genetic changes made within a particular microorganism or those that mimic changes that occur in nature. Attention will focus on those microbial pesticides that "cause significant impacts upon human health or the environment," say EPA officials.

Complying with these new rules will cost industry. For instance, EPA officials project that the initial costs to industry of complying with the proposed TSCA rule will be as high as $2.2 million a year. These costs will drop to $56,000-$460,000 a year within five years, as industry becomes more familiar with TSCA's provisions.

—Jeffrey L. Fox

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Analyzing EU and U.S. agbiotech field trials

OXFORD—The European Union (EU, Brussels) has approved—since the introduction in October 1991 of its directive regulating the deliberate release of genetically modified organisms into the environment—more than 250 field trials of these organisms. Interestingly, genetically modified microbes account for only 5.5 percent of these releases, even though the EU's deliberate-release directive was drawn up originally with such organisms in mind. Yet the EU trails the U.S. by a wide margin. Indeed, since 1987, the Department of Agriculture (Washington, D.C.) has approved more than 860 applications and notifications to field-test transgenic crops alone. In both the U.S. and Europe, herbicide tolerance has been the most-common trait field-tested.

In Europe, oilseed rape has been the most popular crop for plant biotechnologists to modify, accounting for 30 percent of environmental releases. Maize is second, accounting for 20 percent of releases, and sugar beet ranks third, making up 15 percent of releases. Plant Genetic Systems (Ghent, Belgium) is the major driving force behind European releases, with roughly 20 percent of all releases directly linked to the plant-biotechnology firm. Seed companies account for a further 20 percent of releases, with Van der Have (The Netherlands) leading the way with 19 permits. Monsanto (St. Louis, MO) is the leading non-EU-based company, with 15 releases.

France is the favored location for field testing and accounts for almost 33 percent of these releases. This is not surprising, as France has always proved to be a popular site for agrochemical field trials, owing to the different climatic conditions it experiences between its north and south. The French government also has a reputation for taking a pragmatic approach toward interpreting agricultural regulations.

Testing crops that have been modified to tolerate proprietary herbicides—such as glyphosate, gluphosinate, and bromoxynil—accounts for 34 percent of all European releases. Male sterility is the second most popular trait tested, making up 21 percent of releases, while insect resistance ranks third, comprising 11 percent of releases.

The popularity of herbicide tolerance is even greater in the U.S., as fully 41 percent of field trials involves testing this trait. Monsanto's glyphosate and AgrEvo's (Berlin) gluphosinate are by far the most popular herbicide targets, accounting for 42 percent and 40 precent of all U.S. herbicide-tolerant applications and notifications, respectively. Insect resistance is the next most popular trait tested in the U.S., accounting for 22 percent of releases. Improved product quality is the third most popular, making up 18 per-

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